HIT Policy Committee Final Transcript October 12, 2011

Presentation

Operator

Lines are bridged.

Mary Jo Deering - ONC - Senior Policy Advisor

Thank you, operator. I'd like to welcome everybody to the 28th meeting of the Health Information Technology Policy Committee. This is a public meeting of a federal advisory committee. There will be an opportunity for public comment at the end and the proceedings will be transcribed and available on the Web site. I would ask all members present to identify themselves before speaking for the transcript and for those who are on the line. I will at this point take the roll, but perhaps we'll actually go around the room and have people introduce themselves first and then take the roll of those who are on the phone. So we'll start at my left, if you'd like to introduce yourself, Gayle, please.

Gayle Harrell - Florida - House of Representatives

Representative Gayle Harrell, from Florida State Representatives

<u>Farzad Mostashari – ONC – National Coordinator for Health Information Technology</u> Farzad Mostashari, ONC.

Tarzau Mostastiani, ONC.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Paul Tang, Palo Alto Medical Foundation.

Madhu Agarwal - Department of Veterans Affairs

Madhu Agarwal, Department of Veterans Affairs.

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine

David Bates, Brigham and Women's and partners.

Judy Faulkner – Epic Systems – Founder

Judy Faulkner, Epic.

Paul Egerman – Software Entrepreneur

Paul Egerman, software entrepreneur.

Deven McGraw - Center for Democracy & Technology - Director

Deven McGraw, Center for Democracy & Technology.

<u>Charles Kennedy – WellPoint – VP for Health IT</u>

Charles Kennedy, Aetna.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Josh Sharfstein, State of Maryland.

Joy Pritts - ONC - Chief Privacy Officer

Joy Pritts, ONC.

Mary Jo Deering - ONC - Senior Policy Advisor

And do we have members who are on the phone, please.

Robert Tagalicod - CMS

Yes. This is Robert Tagalicod, CMS.

David Lansky - Pacific Business Group on Health - President & CEO

David Lansky.

Mary Jo Deering – ONC – Senior Policy Advisor

And we've had a couple of members just join us, if you would please introduce yourselves.

Christine Bechtel - National Partnership for Women & Families - VP

I'm Christine Bechtel with the National Partnership for Women & Families.

Mary Jo Deering - ONC - Senior Policy Advisor

All right, Paul, I'll turn it over to you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Or Farzad.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

And something has happened, there's a transformation underway that, again, in looking at the microcosm of this one practice, so three years ago he started the transition to an electronic health record and he got a lot of help in the past year from the extension center and the subcontractor of the extension center, which is working with his IPA to help with the customizations of the EHR so that the vendor isn't getting 50 different requests from the 50 different doctors in the IPA, they're doing smart customization so that they don't have templates that change every time they get a new upgrade or it wipes out all their customization. They're doing it on the back end in a smart way, they have a hosted solution, so the doc doesn't have to think about and deal with all the security issues. If they lose a laptop there's new information on the laptop actually. They're helping them get there. Their payments for Medicaid, once the California Medicaid program is up they'll be among the first to get paid under the ... implements and upgrade funds.

And the IPA has also, and the extension center, has also served at the point of convening and trust, so they have in their database every practice of their own little partition off the database so that they don't have to see each other's records. But they brought this IPA together and they said, well now, if you send someone for a referral and they come back and you didn't get the referral back, wouldn't it make sense for you just to be able to see the actual note. And if the cardiologist who you referred the patient to, wouldn't it make sense for them to actually be able to see your record on that patient. And he talked

about, he knew exactly when this transformation in his mind had occurred of how he thought about the medical record, the medical record that used to be his, a medical record that used to be his little notes to himself, and he said I was sitting in that committee room and there was this push to share our records, and he said, and he was choking up, I didn't like it. I didn't like the idea of somebody else looking at my records and me not knowing who's looking at it and why they're looking at it. He said, but I am of course part of what made this happen was that they're part of a group, they've been working together, there's this trust and there are policies in place so that they audit, they record, any time anyone opens up someone else's chart they have a review ..., but he said the main thing was I realized it's not my record it's the patient's record.

And what else is happening in that IPA? They're getting 160% of Medicaid payments because they have reduced avoidable hospitalizations. They applied to be a pioneer accountable care organization, this little doc, 50 person IPA with a lot of Medicaid patients, right, they didn't get it. But that's the direction they're thinking so they're working with a startup to analyze their EHR data to find people who are at high risk of being admitted. They're working with another startup to index their electronic health records back end so they can do a Google search on the EHR and find all the – they showed me, they put in diabetes and they found all the CCDs that mentioned diabetes, all the medications that were linked to it, all the problem lists and so forth in the charts, so they are seeing one typical practice, part of an IPA, part of an extension center, part of a larger picture where we're seeing these transformations happening, and we have a lot of work to be done.

This is still very much in its infancy, but it seems to me that largely unnoticed, maybe not to us here in this Policy Committee, but largely unnoticed to the world at large, which is so concerned, rightfully so, about how health care expenses are breaking the back of our budgets at the state, local, and federal and increasingly in individual people's budgets, it's largely unnoticed that there are these three trends that are happening: the transformation within practices of how patients are cared for, the transformation of how care is paid for, and how patients are engaged in their own health. And these largely submerged massive trends will, I think become apparent in a few years. And if we can work together on those trends, if the payment takes advantage of the IT infrastructure, if the IT infrastructure is being built in a way that it can serve better the needs for patient engagement and for payment and for performance improvement, then I think we really have a chance here of vastly exceeding anybody's expectations of how much health care can improve, improve in its cost, improve in its efficiency, improve in its quality, improve in its safety, and improve in its coordination. The expectations are low, that's the good news. But I'm actually very hopeful, so pardon our appearance, transformation underway, and we at least have some pictures of what this is going to look like. Charles?

Charles Kennedy - WellPoint - VP for Health IT

Can I give you another story?

<u>Farzad Mostashari – ONC – National Coordinator for Health Information Technology</u> Yes.

Charles Kennedy - WellPoint - VP for Health IT

We're launching, and I don't mean this to be a commercial thing for Aetna, other health plans are doing this as well, but we're working with a series of delivery systems around deployment of ACL models in the commercial space and we actually have some clients who have actual health plan products that are private label products, the delivery system's name on it that they're selling, and what was particularly interesting to me was the COO of a delivery system, high cost. If you look at the Dartmouth Health, these guys are outliers. I said, why on earth would you want to form an ACO? You're a monopoly. You're making tons of money. You can keep doing this for some period of time. And he said, look, I understand that the jig is up. And the second thing he said was, I know how to take \$60 per member per month, \$60 out of my cost structure. I know exactly how to do it. I've never had a motivation to do it before until health care reform happened. And he's actually taken those costs out of his delivery system, and because he has a product in the marketplace he gets to reap those efficiencies. The second thing he said was I never really had a use for health IT until I began to take costs out of my infrastructure. So not

only is it happening on a micro scale, it's also happening on a macro scale. It's very early, but I couldn't agree with your statement more. It's happening.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you, Farzad. That was truly inspiring in terms of what we're here for and a picture of where we're going. I can't help but think that we've been going for almost, closing in on three years now, and I think every month and every day between the months there are volunteers and workgroups that are trying to advance the policies and the standards that you talk about that make that happen and make what Charles just described. So that was really important.

To talk a little bit about our agenda today, in a different order, so one is we've got to get people signed up for these programs and so we're going to hear a brief update on the enrollment program, how can we do that both more accurately and more efficiently, so getting people eligible for the program. Then we'll have an update on where we are with the meaningful use attestation, so how is this program going, what is the inflection point, and we've been hearing it's been doubling almost every month so I think we're at that inflection point. Well, it takes more than just people installing software, how do we get data to move around, the very point you raised, and that's where the HIT Standards Committee and their work towards getting us connected, getting us truly interoperable. So we're going to have our update on the summer camp that the HIT Standards Committee has been doing, and I'm sure that will be engaging for us as well.

Then going on to the next stages, the research, the quality reports, things that help us coordinate care, the privacy and security workgroup constantly is working on the policies that have to govern the exchange of this information. We heard a bit about the proposed update to the common rule, and so we're going to close that discussion out this morning, and also what we heard about last month which was ... health, a different architecture for gathering information, reporting, and contributing to the learning health system. Every month we have advances in discussions, because it's hard stuff. We have to get through that but we have to lay this groundwork for another part of the infrastructure construction because all of the small practices can't be working on the interstates, and that's a suitable role for the federal government so that's what we're trying to help with.

Before I move on, you all had a copy of the draft minutes and I'd entertain a motion to approve those or any edits.

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

It's Deven. I didn't have a chance to read them. And since we took up a lion's share, can we preliminarily approve them and then if I have corrections, –

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Sure.

<u>Deven McGraw – Center for Democracy & Technology – Director</u> ... that would be great.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, with that proviso any other comments or motions?

W

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Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, any further discussion? All in favor?

All

Ave.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any opposed or abstained? Okay, thank you. So they're provisionally approved. Our first agenda item is the Privacy and Security Tiger Team to update us on their comments on the ANPRM for the common rule and recommendations on query help, and that's presented by Deven McGraw and Paul Egerman.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I think we only have slides on the second half of our presentation today which is on recommendations on the policy sandbox for ONC's Query Health Project. But we would like to first ask for final approval of the letter of recommendations regarding the use of EHR data for secondary purposes, focusing in particular on some of the questions raised by the advanced notice of proposed rulemaking. There's nothing of substance in this letter that's different from what the Policy Committee saw and approved, but what we needed to do, especially since this letter is going on and being submitted as a comment to the ANPRM was to pretty it up and put it in the frame of being an approach to these issues which is in many ways consistent with but slightly different and we think a bit improved from what HHS has already put on the table in the ANPRM. It was really added framing in response to some of the remarks that you all made, so rather than go through this letter in detail, since you've already approved the recommendations, what we were hoping to do was to ask if anyone had any suggestions or comments or needs for modification and otherwise we would ask for its approval so we can get it in.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any other comments or questions about the revised letter? Larry?

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

Larry Wolf. I'll jump in with a comment and support what we're doing here. I think the notion of saying that to create a learning health system we need to be generating knowledge for the broader good, the larger community, and that historic distinction around research created a clear line there and we're moving that line. I think to say that and look to have that reflected in the common rule is actually a very, very helpful thing and will help us get out of this, I'm doing something new, everyone internally wants to call this research, but I keep having to remind them it's really operations because if it's research we're in trouble. We want them to do the analysis, right?

<u>Deven McGraw - Center for Democracy & Technology - Director</u> Right.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

They don't know the outcome.

Deven McGraw - Center for Democracy & Technology - Director

Right. We want them to do the analysis and we ideally want them to share it.

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

And we want them to share it, exactly.

Deven McGraw - Center for Democracy & Technology - Director Yes.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

So I think that this is a great thing for us to be doing.

Deven McGraw - Center for Democracy & Technology - Director Yes.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

Josh?

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Could you explain how public health is handled in the comments?

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

It's not.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Would it be appropriate as part of the Policy Committee to say that there are extremely important public health uses in addition to clinical learning uses of data?

Deven McGraw - Center for Democracy & Technology - Director

I certainly don't mind adding a sentence. We really did focus on the issues raised by the ANPRM, which focus on research uses and not public health, but if you want us to add –

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

It falls under something that may not be research also, so there's the not research use for clinical effectiveness. There's also the not research use for public –

Deven McGraw - Center for Democracy & Technology - Director

Absolutely, but we were looking at some categories of activities that would never fall in the public health bucket, number one. And number two, we're in that gray area between when they would be considered to be operations or when they would be considered to be research, not anything that would qualify as public health. So it's not a global look at all secondary uses, it's instead examining those uses that are ordinarily characterized as research and then subject to research rules and suggesting that in some cases you might not want to subject some of this work to the same rules that apply to research. I don't mind putting in a statement that says public health is valuable. It didn't come up only because it wasn't squarely presented by the issues. It —

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

It may be helpful to point out that the letter doesn't cover public health, or that -

Deven McGraw - Center for Democracy & Technology - Director

Oh, sure.

Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary

... because what can tend to happen is that people assume that public health winds up as research if it's not expressly explained that that exists as a separate entity.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Sure, absolutely.

<u>Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u>

Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

One of the things that came up in the letter, and I think you explained how the workgroup tried to come up with counter examples of things that would be considered research but didn't get very far in that, and so I just wanted to see if you had any further comments. Did I get that correct?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes. So essentially what we've done is to say that a large majority of us felt as though putting the institution on the hook for stewardship over what happens to data that they're responsible for was the approach that seemed to make the most sense to us, but that a number of people still were looking for a line in the sand about when something that is arguably quality improvement and effectiveness analysis

related sort of crosses that line into research. And we went back and forth over at least a couple of meetings about where you might draw that line and we just could not get there, and we acknowledge that. And we suggest that HHS may want to explore that. But one thing that we clearly could get consensus on is that this notion that the line is at generalizable knowledge or not is not helpful for a learning health care system.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any comments or questions? Okay, so I entertain a motion to approve the letter as revised.

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Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

And second?

W

Second.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any further discussion? All approved?

All

Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

And opposed? And abstained? Good, thank you.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Thank you all very much, and thanks, we will add that. I took notes on Josh's comments, so we'll get that in before it gets submitted.

Paul Egerman - Software Entrepreneur

Great. This is Paul Egerman. I wanted to proceed to our second topic, which relates to query health, although I first wanted to make an observation about Farzad's comments this morning, where he talked about Florida, and California being a leader. I was going to suggest, Farzad, if you'd like to see the leader in payment reform I would encourage you to come to Massachusetts, because we could also show you some very exciting things.

But having said that, what we are here to talk about is ONC's Query Health Project, and this is a project that this group had a presentation on, I guess it was at our last Policy Committee meeting from Richard Elmore. Here is the list of the Tiger Team members, and I want to again thank them. I appreciate Larry's comments about the ANPRM. We had a really very interesting discussion on all those research issues, and a lot of the Query Health discussions follow actually very well from that entire discussion. So I want to thank all these people, including Judy Faulkner and Gayle Harrell, who are here for really a very thoughtful and meaningful discussion on all of these issues. We are supported by, of course, Joy Pritts, and it says Judy Sparrow, who supported us through part of this discussion, but now Mary Jo Deering, and we need to update our slides with Mary Jo, for your efforts in jumping in and dealing with – we consider this group to be fascinating and interesting but you probably consider us to be demanding, but we appreciate your help.

So Query Health, basically the best way I can describe it, I can describe it 100% precisely correctly is the project that ONC is undertaking in some sense at a very high level, like the Direct Project, this is a project that ONC is undertaking, and as a result our recommendations are a little bit different this morning. Lots of times we make recommendations where the intention is to impact regulations. Here, our recommendations are really recommendations related to policies that ONC is establishing, so this is recommendations to ONC about their policies. And fundamentally what has happened is ONC actually

established a set of baseline policies in terms of what they want to do and they asked for our comments. So Joy, you're about to correct me.

Joy Pritts - ONC - Chief Privacy Officer

Just to clarify a little bit, it's policies for a pilot project.

Paul Egerman - Software Entrepreneur

That's right.

Joy Pritts - ONC - Chief Privacy Officer

Which is looking at means of obtaining information for research purposes in a distributed model.

Paul Egerman - Software Entrepreneur

Right, so we will talk a little bit about what the pilot project is, but it is exactly right, and so thank you for that clarification. Policies are related to a pilot project and also we on the Tiger Team want to thank ONC for bringing this to us early, in other words, bringing it forward to us early so we could have this discussion so we could be informed as to what ONC is doing that I think has been very helpful to ONC also to see, and to the people working on it, to see what issues we felt were particularly important in these policies and where the emphasis should be. Having tried my best to describe that now, Deven's going to give a quick review of the pilot project.

Deven McGraw - Center for Democracy & Technology - Director

Yes, a very quick review. Again, and Paul and I are going back and forth because I talked way too much on the last meeting, you've all seen or you should have seen the presentation by Rich Elmore of ONC at the last Policy Committee meeting about just what Query Health is. And we're not going to repeat that, but we want to remind you of two relevant facts that are important to keep in mind as we review the recommendations. The model is a distributed network, which is that the questions are brought to the data, not that the data is collected centrally in order to answer the question. The data holder retains control of the raw data and performs the analysis and then reports back the answer to the question, either in aggregate form or in de-identified results. And the initial set of queries in this pilot, as Joy mentioned, will be developed by the Query Health Clinical Workgroup. But each data holder has the option of deciding whether or not they want to participate in any particular queries. So the data holders maintain control of their data, including the decision about whether or not they're going to participate in any particular query, and so Paul will take you into the first set of recommendations.

Paul Egerman - Software Entrepreneur

So for a set of recommendations basically it relates exactly to what Deven just said, that data holder, or we're calling it the disclosing entity, what has been proposed is that the disclosing entity gets to decide whether or not to run a particular query and to release any results, that's always under the control of the disclosing entity and the data holder, and our recommendation was to basically endorse that policy. We felt it was consistent with the core values that we had established in some of our earlier privacy and security work, where we talked about trust between the patient and the healthcare provider and the patient's expectation that the healthcare provider would keep their information confidential and secure. And it's also consistent, as Larry had suggested, with what we just talked about with the whole ANPRM and research activity, where we said use and disclosure of health information from EHRs ... for secondary purposes, is the responsibility of the provider entities. So that's the first recommendation.

Deven McGraw - Center for Democracy & Technology - Director

Then the second one, thanks, Paul, is that data that's being exchanged by the disclosing entity or the data holder will either be mock or test data, remember this is a pilot, aggregate deidentified data sets are aggregated limited data sets, each with a data use agreement, so that's even in circumstances where they're not required by law; limited data set requires a data use agreement, de-identified data does not. The policy that ONC is proposing is that both would require a data use agreement, or a public health permitted use under state or federal law which may be identifiable information where permitted by law. So that's what ONC had initially developed in here with our response, that we agree that the data that's being exchanged should be either de-identified or an aggregated limited data set with a data use

agreement in place even for de-identified data. And this agreement ideally should, at a minimum, restrict the use of the data, restrict the recipient's use of data that they receive from Query Health to facilitating Query Health and prohibit them from re-identifying the data.

Now, the Tiger Team approved this recommendation but subsequent to approval of that recommendation we were asked by ONC, and Rich Elmore in particular, to hold off on finalizing the recommendation that the data use agreement restrict the recipient's use of the data to facilitate in Query Health, and his concern is that in this early pilot phase where they're trying to create a program that is potentially attractive to a broad range of entities, again this is going to be voluntary participation, and they are concerned that a hard and fast rule that says you're not allowed to use this data for anything but Query Health could be a disincentive for some providers or entities who would otherwise be interested in submitting queries through Query Health to jump in and do so.

The Tiger Team has reached consensus on the recommendation that is in the slides. And I think some of the concerns when we discussed this were we don't want Query Health to become the pipeline through which entities receive data that they otherwise would not have had access to potentially, and then to allow them to use it for a broader range of purposes than just Query Health. And certainly in discussions with ONC I think they understand this position and I think it's a bit of a concern that this approach, which draws a very hard line in the sand, may be a little too restrictive to impose early on and that rather than impose this now that we might hold it in abeyance, set it to the side until the pilots have had some opportunity to operate and they see whether this particular recommendation might in fact become a restriction.

One of the other options that he suggested might be more feasible would be that specifying that the data use agreement must specify with particularity how the data can be used, and that any other use not specified in the agreement would be prohibited. So that's not an open-ended use of data, that's defined, allowing the entities to define how their data that's submitted as part of Query Health is allowed to be used by a recipient entity. I have some questions about whether that's scalable, because that requires a negotiation with each and every entity, but nevertheless it is another option for accomplishing restrictions on the recipient, which clearly was a priority, or at least the consensus of the Tiger Team based on our call. You don't want to open a channel for this data and not have some set of expectations with respect to how the recipient can use the data once they receive it. Joy, did you want to —

Joy Pritts - ONC - Chief Privacy Officer

I want to just add a few points here. On the call Rich did point out that he did not know what the effect of this restriction would be at this point, and that continues to be the concern because this is talking about aggregate data, some of which is de-identified, and so these are restrictions that would go above and beyond what normally is required for aggregate data. You can see where aggregate data could be as simple as 20% of our population has "X" and so there's a lot of nuance here that I think needs to be explored and that's really what they were asking for is that there be a little bit more discussion on that particular point before there would be a recommendation made.

Paul Egerman - Software Entrepreneur

That was my question also, Deven, to what extent is the information that's being returned is summarized information, on the example of what percent of your patients had flu-like illnesses last week and the answer is 20%.

<u>Deven McGraw – Center for Democracy & Technology – Director</u> Right.

Paul Egerman - Software Entrepreneur

Particularly joined with the small cell size rule, that we'll get to, that seems to take out any particular concerns about individual privacy.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Well, yes and no. Certainly in the case example that you're raising it absolutely does. That's just a number. There's no underlying data there. But I don't get the sense that you envision that Query Health, that those queries will be limited to queries that can be appropriately responded to just with numbers. And hence the policy goes a little broader and says, it could be an aggregated limited data set or it could be de-identified data, which could be down at the individual level, but of course stripped of identifiers sufficient too.

We had originally planned to go through all of these and then talk about the ... innovations. I wanted to make sure that people understood that this one we had been specifically asked about, but I yield to the chairs about whether you want to have more dialogue on this before moving forward, or how do you want to do it?

Paul Egerman - Software Entrepreneur

I'd like to make just a couple of comments. I'd say first even if it's aggregate summary data there still could be issues. To pick up an issue that is in the news, all this business about HPV vaccinations, you could see how people would be upset if you did a study relative to that and the results of that were ultimately used for political purposes, as opposed to what you thought was a medical application. So there could be a lot of ways that one could be concerned about how the data might be used. The other observation I would make is we are simply at this point in time commenting and giving feedback to ONC about its policies, so I suspect that this discussion is by itself useful to ONC in terms of understanding it, and the original policy that they put forward was very restrictive and we said we agreed with that, and then the way I look at it is we decide well, that's what we're going to simply say right now and then if ONC wants to come back to us and say well, here's an alternate approach, here's what we have learned when we tried to apply this, it was too restrictive, that the ... that Rich Elmore has, whether or not it happens or it maybe it's too restrictive and he wants to do something different, and it's helpful to know this is an area that ONC might find too restrictive. So I'm suggesting that perhaps one way to look at this is with that knowledge we could simply say this is okay as it is now. I don't know what you think about that.

Deven McGraw - Center for Democracy & Technology - Director

Yes. So, Paul, how do you want to move forward? Do you want us to go through the other pieces of this, or do you want to –

Paul Egerman - Software Entrepreneur

Unless they're clarifying on what the statement means, then why don't we go through and then we'll ..., okay?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes, because we're not done with the controversy.

Paul Egerman - Software Entrepreneur

Yes, okay.

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

As usual.

Paul Egerman – Software Entrepreneur

So on the next slide we have two more recommendations really based on that previous data exchange concept about the data being exchanged, and these three concepts you have to keep that in mind as you look at these. Basically we're saying that during the pilot phase of Query Health ONC should implement policies that are restricting the data recipients from using information shared for purposes other than to address the query. This is basically another restatement of what we just talked about. The next statement says that these restrictions should be part of the daily use agreement, but as Query Health scales beyond the pilot phase there probably needs to be some governance process for this entire project for compliance with data use agreements and other policies, and we simply suggest that the experience that we're going to learn from doing the pilot project will probably inform us about various issues relating to the type of governance that might be needed to oversee Query Health in the future.

Deven McGraw - Center for Democracy & Technology - Director

So then the final recommendation, not final on Query Health but final related to this issue of data exchange and data exchange policies is that although HIPAA allows identifiable data, and so I'm really glad that actually Joshua and Farzad are both here for this one, although HIPAA allows identifiable data to be disclosed for public health purposes, not all public health activities actually require or need identifiable data. So the policy really should be that the disclosures are in the least identifiable form necessary to address the particular secondary data use query, which is actually consistent, we think, with the minimum necessary standard under HIPAA. In other words, the data disclosed in response even for queries for public health would be a limited set of de-identified data unless greater identifiability of data is specifically needed, and certainly the loss supports the disclosure of that in that case. And maybe the flu count example is one where reporting instances of the flu you really only need the numbers and maybe some geography information, but not necessarily who that person is even though some laws would allow you to disclose it by fully identified.

Paul Egerman - Software Entrepreneur

Great, and then the last topic relates to this concept of small cells and basically what it says here is the proposed policy from ONC that cells with five observations or fewer will be either blurred or basically the accuracy of the information in this cell will somehow be reduced, and what is cited here is a data release guideline from the government as to how to do this. The reason for doing this is to make sure that you don't have an inquiry where you, in effect, ask successively specific questions that allow you to identify an individual or learn a lot of data about perhaps one individual or a group of individuals. So that's the reason for doing this small cell blurring, and our recommendation was to simply agree with that. And there's an important phrase here I want to point out there when we said we agree with this policy as a method of reducing the risk of identifiability, but one of the things that we wanted to make clear to everybody from our discussions, and thank Dixie Baker for helping us understand that, is that this process is like everything else, it's not perfect. In other words, it helps to reduce the risk of identifiability but it is actually statistically still possible, if one is very determined, to find a way to use a successive series of small cells to do the things that you don't really want to do but it is still possible to do.

Having made that observation, we are still agreeing with this policy. That actually completes our recommendations on Query Health and I guess we're asking for approval, although I'm not sure what we're going to do about that one issue, but I guess being very determined we're going to ask for approval anyway.

Deven McGraw - Center for Democracy & Technology - Director

Yes. Again, they are the recommendations that the Tiger Team approved and so we're presenting them for your approval, and I'm sure we'll have a nice discussion about this.

M

I do wonder if a distinction should be drawn between summarized information and de-identified information and whether the policy guideposts would be different if what comes back is — I see your point, Paul, about the potential, but my sense is that if it's a number, you know x out of y, you can publish that number for whatever purposes. I can publish and say as part of my research study we found that 25% of teenage girls got, whatever your example, got this vaccine and someone else said then use that for whatever purposes they choose to use it. I think it stretches a little bit the Privacy and Security Tiger Team's main area of interest here, which is around the protection of personal health information and the fair information practices around that once you start to get into summarizing for I wonder if it might make sense to just segment that recommendation and to have a little bit of a broader flexibility in terms of how summarized information gets treated versus de-identified and potentially I guess re-identifiable.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

We didn't squarely present that to the Tiger Team, but I personally think that that's a reasonable way to approach it. I'm not sure that meets Rich's concern, which is largely one of do we want to draw any line in the sand as early as the pilot phase. My sense is that we want to signal that in fact there should be some restrictions on recipients of data, and maybe, Farzad, your compromise is the way to do that, at

least for now. We can always be asked to revisit, is the point that Paul made, and we've done that before.

Paul Egerman - Software Entrepreneur

The context of this, these are recommendations to ONC about the pilot, so in a sense the policy recommendations to this pilot project from which we all hope to learn. Judy, Gayle, Josh, and then Larry. Judy?

Judy Faulkner - Epic Systems - Founder

First, my apologies for not bringing these up during the meeting, but the first one is on the recommendation that you can ask questions beyond the original question, and it seems to me that a huge amount of research is iterative, you ask a question and you get some answers. You look at it —

Deven McGraw - Center for Democracy & Technology - Director

Judy, that's not what the recommendation says. We didn't say you couldn't ask more questions; you'd have to submit them as queries. It's just when you get your response what are you permitted to do with that data.

Judy Faulkner - Epic Systems - Founder

Okay, let me ask it differently then. Let's say you get the response and the response was based on what Farzad said, but as you're looking through that data you think, gee, there seems to be an awful lot of people in the 30-40 category, it looks like 80% of them, but that's just eye balling it, can I do another query on that to isolate the data more, or is that not legal if I haven't asked that question to begin with?

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

I'm not sure I totally understand the question. Do you want to submit another query, or do you want to take the data you got and re-analyze it?

Judy Faulkner – Epic Systems – Founder

Let me tell you what -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

... enough data back that you could actually -

<u>Judy Faulkner – Epic Systems – Founder</u>

Riaht.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

... subject it to another analysis.

Judy Faulkner – Epic Systems – Founder

I want to take the data back because in answering the first question, which happens all the time, there's a second question and a third question and they each cascade into the other as I'm getting more understanding of what the data is telling me.

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

Right.

<u>Judy Faulkner – Epic Systems – Fou</u>nder

Which is traditional research.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes.

Paul Egerman - Software Entrepreneur

It's an interesting question. I actually assumed that that would be allowed.

Deven McGraw - Center for Democracy & Technology - Director

We did specify, I think, the recommendations as stating, not that you would get the data from Query Health and then you could use it for any purpose permitted by law, but instead to say you got the answer to your query and that's what you used it for. It's a very good question and one that I think the Policy Committee should deliberate on because we do have an issue where entities are trusting that the data that they submit is going to be used for the purpose for which they agreed to answer the question. If the recipients are then permitted to use it for purposes beyond that, again, always in the confines of law, do we have a problem with that or do we then confine that to say to the query that they submitted or queries that are related to the query that was submitted. We're looking for boundaries here because I think there was a level of discomfort with suggesting that one could use Query Health as a pipeline even for deidentified data without any sort of rules about how you would use that data once you got it.

Paul Egerman - Software Entrepreneur

The way I'm interpreting what you're saying, Judy, it's sort of like if your first inquiry said something like break these patients down by people aged 30-40 and you look at the results and you say I really would like more of a breakdown. I need to know, every year, 30, 31, every year between 30 and 40 because I didn't expect the results that I got.

Judy Faulkner – Epic Systems – Founder

Yes, exactly.

Paul Egerman - Software Entrepreneur

Yes, that might be the sort of thing that possibly would be the case. So it's just a successive query based on the original ... which I don't know how they're going to do that technically but I thought that would be —

<u>Judy Faulkner – Epic Systems – Founder</u>

And it may not be the same thing.

Paul Egerman - Software Entrepreneur

... to be able to do that.

<u>Judy Faulkner – Epic Systems – Founder</u>

You may break it down by 30-40 and then find out, for example, that it's only males or it's only pregnant women, or something like that, and how do you continue to look through that data.

M

I think it's not actually about the uses of the data that you get. I think this is more about the first item, which I think few people have a problem with, which is whether or not to run a particular query or any follow up queries to the initial query will be under the control of the disclosing entity. So I think how this gets up, and we have to leave a little flexibility for the project team here to figure out how they're going to operationalize this and whether they want to have a larger description of what the research question is under which a number of queries could be run, or whether every single specific sequel query ... or whatever equivalent of it has to be approved. But I would suggest that we step a little bit at a higher level in terms of letting some flexibility in terms of how those things actually will get worked out. But the concept that the Tiger Team has set forth is the disclosing entity decides whether they're going to run a particular query or not, whether it's an initial query or whether it's a further articulation of the initial query.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right, yes. I thought I heard something different in Judy's question. Clearly recommendation number one is about queries, and we don't place any limitations on that other than to say people participate if they're comfortable doing so, however it's defined.

Paul Egerman - Software Entrepreneur

I think it's actually well covered. I'm reading your recommendations, and to answer Judy's question, I think they're well covered in two ways. One is you say, Judy, I get the results of a query and then I want further information about the breakdown by decade. That's a separate query. It's covered by recommendation one. I get a result and my result does include actually whether they're pregnant, for example, which happened with the flu. I can further analyze the young women who are pregnant because it's still for the same purpose. So I think these are all consistent with what's been recommended but it allows for exactly the scenario that you proposed. Gayle?

Gayle Harrell - Florida - House of Representatives

I think the Tiger Team did an excellent job in really delineating all the specific issues involved here, and I apologize for not being on the last one, I'm a little tied up with the session going on. But I have to say that I think that the main question is what are you going to reuse that data for. That's where the rubber meets the road. And I think that needs to be articulated in that data use agreement so that we make sure that the disclosing entity knows exactly what is going to happen to that data. That's where the issue is. And that's where on recommendation one, unless we go with recommendation one I have a problem. I think you've got to know what the use is and agree to that use before you release that data. I'm very comfortable with the recommendations as they stand right now.

Paul Egerman - Software Entrepreneur

I think you're supporting what the Tiger Team came up with. Josh?

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

It would help me on the public health to understand what the anticipated use of a pilot is for public health before understanding whether this is even necessary kind of crossing this bridge and then we can talk about the substance. But I was listening to the discussion on the phone last time and I wasn't quite sure there, it sounds like it's a research pilot, but is it a public health pilot? How would that work?

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

I think that the concept is that for a variety of other uses of data routinely collected for clinical purposes, for example, whether it's quality, whether it's research or public health, it's a common problem. To analyze the individual information, the individual data, do you have to put it all in one big pot and then analyze it. Or, whether for public health or quality or research the questions can go to the data holder. In the public health context you may have a question about what are the rates of immunization in different groups within the city, so in order to answer that question from electronic health record data, you can either ask every electronic health record holder to submit the raw detailed information line list, this person got a vaccine, this was their age, this was their zip code and so forth. Or a query could potentially go to the data holders, each of the large holders of the information, and to say tell us your vaccination rates. So it's the —

Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary

I certainly see the potential use of a distributed network for a public health system. This is sort of like proposed policies for the pilot, as I understand.

<u>Farzad Mostashari – ONC – National Coordinator for Health Information Technology</u> Right.

<u>Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u> So are you –

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

The pilot is to develop the standards predominantly for how questions can go and how can they be responded to and work on some of the trust issues, the technical issues, the governance issues potentially that would go along to actually operationalizing something like this.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Okay, so it could be that you want to think through what the public health use of the data is as part of the pilot?

<u>Farzad Mostashari – ONC – National Coordinator for Health Information Technology</u> Definitely.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Then I would say that I think that it's such a different paradigm, the public health use of data is, than the research use. And I think what you've got here is a recommendation that is not all that inconsistent from a research approach, which is people should only get the data that they really need to do the research study. It's the same kind of approach. Public health's use of data is often quite different from that. We get syphilis reports, HIV reports by name, we are setting up a system, and almost every state has one. that gets every prescription for a controlled substance, controlled opiates reported in, we are responsible for enormous amounts of highly private data and in part that's because there's a level of accountability on the public health entity that does just not exist for researchers who are doing projects. Anything that we do we are entirely, completely accountable for. And I guess my preference would be to rely on that basic system accountability that exists in general rather than try to replicate it in a whole new system of accountability that would be potentially - I'm not sure how you would negotiate this kind of thing with public health and we have really the ability for any patient, depending on the situation, we have the ability to go in and pull their records. It's just a completely different paradigm, whether we should be using a research paradigm for this as well. And a more narrow, if you're not with me on that I would say that really my preference would be that the public health approach to data should be consistent with the public health approach to data that a particular state has, as opposed to a one-off determination for every little project that has to get analyzed.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

A question, Josh, do you think that instances where public health does not have the authority for collecting the identifiable information would then fit more neatly into this paradigm?

<u>Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u>

No, more neatly perhaps, but I'm not sure as a research paradigm it's one that I would want to go down, which I think is what this is. If you were going to do it, I would add one, this is my last thought, people aren't totally with me there, which I figured they might not be, which is that public health has a different, research, you don't know what you're going to find, there's not necessarily the time issue that a public health department has when you're dealing with something. So if there is an emergency that's coming up you need to be able to act, you're accountable to the public, you've got to move, I think that I would, at a very minimum say that there has to be feasibility criteria in here that it is not, I think, a great idea to set up the expectation which might be the case for research projects, that we're going to spend time really negotiating exactly what the minimum necessary set is, as opposed to saying, what is the time that public health has, what is the goal that you have, what is feasible in order to accomplish the goal. It may be that you could create a whole new way to analyze data that would get it to you in a slightly less identifiable way, but the fact is you need to do this for public health and it has to be done. I think that concept should be part of any discussion of public health data above and beyond the basic, like the minimum necessary ... process where you're negotiating over the minimum necessary. And where there's a public health issue that comes up you may not be able to do that. I don't think it's necessarily the right frame —

Deven McGraw - Center for Democracy & Technology - Director

Right, just so you understand where we were coming from, I think we're probably handicapped by the fact that we don't have a set of pilot queries on the table so we can judge them specifically. I don't think we ever intended to suggest that public health reporting of cases is authorized by law, where that data's identifiable. I don't think we were trying to step on that in any way. I think we were looking at not exactly the scenario that Farzad suggested, which is where there isn't authority to collect the data at all, but where the public health authority is more general in nature and there's a query that isn't tied to a specific mandate to report cases, but is instead looking at, say, in the many... pilot projects where they have in fact imposed this policy that they are looking at post market safety surveillance questions for approved

drugs and devices where they're coming up with queries that aren't already embedded as legal mandates, but certainly are within their scope of authority and they've decided that at the early stage of signal detection they don't necessarily need the data to be identifiable.

And it's coming in to the data center, to Harvard Pilgrim, and in order to give counts it doesn't mean that they can't go back and perform their public health function and notify people if in fact there is a significant safety issue. But certainly in discussions in the Tiger Team there were a number of people who, notwithstanding that public health is accountable through other mechanisms than the private sector collectors of data are, express some concern about the degree of identifiability of data collected for public health purposes. So what we were doing was reacting to a blanket statement from ONC that said, oh, when it's public health regardless of what kind of query it is it can be identifiable. We were just saying, hold on a second. Let's not assume that the query needs identifiable data, but not intending to step on somebody's use of Query Health, even in a pilot phase, for a legitimate reporting obligation that either requires or is facilitated, ease of facilitation with identifiable data. So maybe this is just a question of framing, I don't know, but I just wanted to give you a sense of where the dialogue had been on this issue.

W

Farzad, I think it would be useful if we explained a little bit about how the pilot project structure works, because I think that might shed a little light on this. You can do that, or I can do it in my limited knowledge here, but –

Deven McGraw - Center for Democracy & Technology - Director

We might have Rich on the phone. He was going to dial in.

W

Rich, are you on the phone?

Rich Elmore - ONC

Yes, I am.

W

Okay, well the why don't you do it because it's your project.

Rich Elmore - ONC

First of all, thanks, everyone for engaging in this. This is really important and will be very helpful to us as we move forward. We're at the stage in the project where we developed a generic user story, which the community is now refining, and building on top of that several different specific user stories for different kinds of possible applications; one is investigating vaccination rates, one is an expanded analysis for diabetes, one is myocardial infarction and quality measures and patient, just a whole bunch of different stories that have been built, and the idea is from those we can get an architecture that makes sense for the project. Then we're going to down select from that one or two that will actually be the foundation for what we build out for ... implementation for pilots. That decision about which user stories best meet the various criteria needs of the project is underway now and it's not decided yet by the community but we will have visibility to that in the next month or so. What we expect is by the end of the year that we'll have some visibility to the reference implementation, to the priority user stories, it will be the foundation for the pilots, and early next year be in a position to be able to say, well, if this particular policy recommendation around restrictions on ... use agreements, whether or not that would have any impact on pilot participation we would probably be able to better gauge it at that time. Have I answered the question?

Paul Egerman - Software Entrepreneur

Could I try? In a sense it's nice if you can draw an extent statute to regulations to answer the question and make it simple. Your original reason for not having this extraneous channel and having people reuse or repurpose data was one, because we do not control what happens afterwards. In the public health sector they already have statutory, both authority and obligations in terms of not misusing that

data. So would it be possible to use that and say that's why it's okay for the public health agency to query for information and make their own judgment about how identifiable it needs to be.

Deven McGraw – Center for Democracy & Technology – Director

I don't think it was just the issues of recipient use that drove this recommendation. I think what drove this recommendation was a blanket assumption that any public health use would require the release of identifiable data, and people pushed back on that and fully recognized that in a multitude of public health purposes, yes, you need identifiable data. But surveillance, counts, you don't necessarily need to get that identifiable data and we didn't think we wanted to just leave a blanket exception for public health without suggesting that any query really ought to be, you get what you need to facilitate the purpose for which you're asking the data. And in a public health context certainly there is a wider berth for that data to be identifiable, both because people generally recognize public health authorities get data and there are some other countervailing considerations with respect to how they are restricted in using data on a going forward basis. But it wasn't just on the back end, it was also on the front end. And again, reacting to really the policy that ONC put forward which is to say oh, if it's public health therefore we're not going to place these same restrictions with respect to how that data gets disclosed, and I think we were just suggesting let's not say that all public health uses by default require identifiable data, but instead suggest that the data needs to match the needs of the query.

<u>Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u>

One way to potentially bring people together, if your purpose here is not to limit the existing legal authority or be an addition then make that just explicit and say that this would not limit what public health can accomplish under its own authority. That alone would be helpful, because there may be cases where in Maryland we would need to do identifiable and people say, well, tell us why it has to be —

<u>Deven McGraw – Center for Democracy & Technology – Director</u> Right.

<u>Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u> And it's like, look, I've got plenty of authority in the healthcare segment to get that.

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

I can get it from you directly ... now.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Right. I think that gets us pretty far away along because public health generally has a lot of authority.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

The Tiger Team has had a lot of deference for statutory authority.

М

But in this case it would be very important to explain, if there's a statutory authority to how that works, this isn't on top of that.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

That's not a problem. If you look at this at a higher level, this pilot project from a privacy and security standpoint is wonderful, because it's basically a technology project where you say we're going to bring the questions to the data and as a result you're going to have a lot less data flying around. The less data you have flying around the less risk you have. That's my very high level, crude view of the thing, is the more you keep the data between ... at the provider site, the more trust people have in the system. So that's what this project is all about and all we're saying is just be true to the concept of the project. When you ask for data, you've got to get the least amount of data that you really need because the fundamental concept is excellent. The implementation is not going to be easy. What they're trying to do is really very tricky from a technical standpoint and from a governance standpoint, but we just had this whole long discussion and there's going to be a lot of other discussions. This is wonderful, but it's not intended to interrupt what public health is doing. It really has no impact on public health.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

I think, Josh, maybe we can agree that we have agreement.

Paul Egerman – Software Entrepreneur

I just have one other part of that, which is if there's a way to slide in the concept of feasibility or time, then for public health it's not just the most possible thing which then comes back to us and created a whole new system, but that to the extent that it's not covered by law there should be an obligation. I agree with you, having been involved in some of the sentinel stuff, that there's not a need to do things, we shouldn't do that. I wouldn't want that. But at the same time sometimes there is a feasibility issue that becomes a challenge. Gayle?

Gayle Harrell - Florida - House of Representatives

I wanted to jump into this because there certainly are state statutes that restrict what public health can do within specific states, and it varies state to state as to what the responsibilities of public health is, but when you look at going beyond those statutory regulations and authority of public health, when you get into some endeavors that I could see when opening the whole door that Josh was talking about that the public gets very nervous when it comes to that kind of data in the control of government entities. So you have to realize that public health is the government, and when you wind up opening a lot of perhaps non-statutory authority endeavors then you get a lot of pushback and the public gets very nervous. A good example is prescription drug abuse and getting statutory authority to look at the prescription drug history of patients and then you're crossing a line where you wind up, if you allow data mining essentially by government into prescription issues and knowing who takes what medication and we're now collecting information on schedule drugs or psychotropic drugs or whatever, it gets very scary to the public out there. So I think other than statutory authority where they have the ability to look at information and do that data mining, we are crossing a line that becomes very difficult. Just a little bit of warning.

Paul Egerman - Software Entrepreneur

I think we have folks on the phone who have been trying to jump in here as well.

Robert Tagalicod - CMS

Hi, this is Rob Tagalicod. Good morning. This is a very good discussion, by the way, and I think something that CMS and other folks in the department have been working on. I'd just like to offer maybe three or four thoughts really quickly. You know, rather than recreate the wheel, and perhaps the folks in the Tiger Team have already considered this in terms of the pilot, CDC and CMS clearly have some experience in it, particularly in constructing data use agreements, business associate agreements, etc., and as well as FOIA, and data requests come in in very many ways, so I think it may be worth your while to take a look at what our practice is and where you can beg, borrow, and steal, if you will. Because we do follow a rather prudent conservative way of looking at minimum and necessary and so it may be well worth it to inform that process.

In terms of the public health approach, the question has come up for us, interestingly enough at the same time, of informed consent and the ability to opt in, and not necessarily just research, we know that under the authorities of Title 18 as well as the Affordable Care Act have opened up a world of data use and also hence data requests from external parties other than federal partners. So we're engaged in the conversation internally but it may be worth your while so what does it mean when we want to use data and what kind of consent do we need in order to do that and is it doable? And that gets to an operational question. I agree with the communication piece around it, or at least the implicit communication piece of data and data mining and what that looks like, and dare I say it looks like Big Brother, and so I think we need to be very careful about how we do that and how we message it and how we construct this because there is something that's beyond just the process, it is about how we communicate this out to the public.

My last point is, and someone had mentioned about feasibility time, it's also the resources. Our experience is that it does take a lot of resources, both in terms of staff time and dollars in order to crunch these numbers and so I think that's well worth considering as part of the equation and maybe as part of the pilot of what that means and what the impact of it is to our respective organizations in order to get that

data and to be transparent, there's that value. So those are some of the things that we've been struggling with and I'm sure we're going to be informed by the process here today. So thank you very much.

Paul Egerman - Software Entrepreneur

Larry?

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

A couple of things, kind of general comments. I'm really enthused that we're doing a pilot and that we don't know what the answer's going to be and we're going to learn, and that all too often we've been jumping in to create regulations before we've had a chance to actually try something and see what happens and then see how it scales. So I think that's great that we're doing some pilot work here.

I also think that we've got really innovative technology here, that we're actually using the EHRs in a way that they enable our ability to ask questions that we couldn't ask in a paper world and allows this notion of can we do distributed research, can we ask questions where the data stays where it is, the data holder is responsible for the data, we're creating a methodology by which the query can come in and we can assess it, and then we can run it and we don't have to spin up a whole development effort to find the data, and to embed that in the EHRs, this is all really terrific stuff. I also think we're building on our earlier principles of that the data holder has a continuing responsibility. He can't run any requests. You need to look at it, I think particularly around the purpose of the data, the purpose of which we're asking these queries and using it, that really in terms of the trust that that data holder has with their patients, with their constituents, that they need to have the dialogue, they need to have the discussion so there's informed engagement, informed consent of how the information's being used.

So I think it does get to the notion of additional uses beyond the purpose that the recipient of the summarized data might do. It might identify me as a class of individuals and so I might not like how that's being handled by the person who got the data, I may or may not choose to opt in or opt out, but I think that we've seen historically that people get pretty pissed off when their information is used in ways that they didn't know it was going to be used, and they just wanted the courtesy to have been asked. So it's not like I would have said no, I just wanted to be asked. So I think there's an important principle here that we can continue to build on.

On the flip side, though, I'm sort of curious, since we're doing a pilot and we're going to be learning things, maybe we should be pushing the envelope of what is it to have de-identified and re-identifiable data. And so perhaps we want some of the researchers to ask the questions that the white hackers, if you will, attempt to do and say can you break this data set.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

If that's what you're testing there; if that's what you're testing.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

Right, to explicitly consider that as one of the things the pilot might look at. Because the flip side is then how secure was the data, how private was it.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

What I also heard, though, was that there's a technical point to that, there's also a policy approach to that which is to say you may not re-identify or try to re-identify and there are implications if you do. I think –

Paul Egerman - Software Entrepreneur

I agree with the policy.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

Yes.

Paul Egerman - Software Entrepreneur

I think we should have a policy piece. But I also think that given that we're running a pilot it might be useful to consider can I break in and to consider that within the scope of the pilot. Judy?

<u>Judy Faulkner – Epic Systems – Founder</u>

Forgive me if I was either dense or inarticulate, one or the other, I'm still going to go back to that original question I have because I don't understand it. I'm the recipient. I have a query that the disclosing organizations are sending me data sets, they're limited, but suppose there's 400 different organizations that have sent me those, and my query was what Farzad just had said earlier, a very specific query, I get these 400, and I understand that the disclosing organizations can do more, but I'm the recipient and I have aggregated now all this data together in one big pot and I asked my question and it seems obvious that I didn't ask it right, that there's some more questions to follow up. But this says "restrict the data recipient from using information ... for Query Health for purposes other than to address the query that the disclosing data entity data holder has agreed to." And that's my —

Deven McGraw - Center for Democracy & Technology - Director

How about if we said the "query or queries?"

<u>Judy Faulkner – Epic Systems – Founder Paul Egerman – Software Entrepreneur</u>

Well, I don't think ahead of time you can figure them all out. I think -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Judy, if you need more data, you're going to have to ask again.

<u>Judy Faulkner – Epic Systems – Founder Paul Egerman – Software Entrepreneur</u>

I'm wondering if you can -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

It depends on how the guery -

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

... the query or the reasonable follow up queries.

Deven McGraw - Center for Democracy & Technology - Director

If the original query is relatively broad, I think Farzad raised this point earlier, then you're going to get data back that's going to probably give you a little bit of freedom with respect to targeting different questions to the data that you got.

<u> Judy Faulkner – Epic Systems – Founder Paul Egerman – Software Entrepreneur</u>

Right, if it's -

Deven McGraw – Center for Democracy & Technology – Director

If your query is narrow and you need more data, the premise of Query Health is that the participants decide when to participate.

<u>W</u>

Can I broker this?

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

Yes.

W

Because I think what the issue here is that Judy thinks that the way that this is written would limit people from using the data they received to generate additional queries and she would like that clarified.

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

Oh, okay.

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

That is correct. And also -

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Thanks, Joy.

Judy Faulkner – Epic Systems – Founder Paul Egerman – Software Entrepreneur

... perhaps we have a differentiation on how we're using the word "query." I think technically it means a specific search criteria. And you're using it broader to mean a general question, or perhaps not general but you're meaning it more as –

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes, I'm not using a mathematical -

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

I think that's perhaps where the difficulty lies.

Deven McGraw - Center for Democracy & Technology - Director

Okay. I just went to a whole conference where we discussed how policy people don't talk to math people and we need to do so more often. So this is perhaps an example of that. I think we can phrase it in terms of the research question and certainly being able to use it to formulate another research question would be consistent. I also just thought of a potential other option for dealing with the recipient, and I may be conceding too early but I'm going to throw it out on the table in case it's going to mess up us moving past this, which is that we would say to ONC even in this pilot phase you should for any given pilot question or questions that you are sending out the door there ought to be a process whereby restrictions are set on how the recipient uses the data. And those could be consistent with the type of question that's being asked of the data rather than saying we draw a line in the sand and it must be related to the query. I think that's the thing that makes this most comfortable, but if we gave a little bit of flexibility again in saying that for each query that you do in the pilot you ought to come up with a set of permissible uses of the data by the recipient and nothing else and re-identification would be prohibited and that would allow you to tailor it to the query, give you some flexibility, and also keeping in mind that inevitably it's always the decision of the data holder about whether those conditions are satisfactory to them or not.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

I think, Deven, what I'm hearing, actually for clarification, it's not that for each particular query you tailor a particular policy framework, but rather there may be classes of queries.

Paul Egerman - Software Entrepreneur

That's right.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes.

<u>Farzad Mostashari – ONC – National Coordinator for Health Information Technology</u>

Okay.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

That makes even more sense.

Paul Egerman - Software Entrepreneur

That's right, that's right. Because that also interrelates with what Judy is saying, in other words, you don't want to have to sign a whole book load of agreements just to say can you break it down by gender.

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

....

Paul Egerman – Software Entrepreneur

Yes. ... come back.

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

Query is very specific. It's more specific than -

Paul Egerman - Software Entrepreneur

Yes. Gayle?

Gayle Harrell - Florida - House of Representatives

One more thing I want to jump in on is governance. We have to admit we make laws, we make rules, and we make regulations because there are bad actors. And I think the governance issue is extremely important and ONC, in running a pilot project of this nature, really needs to look at what they're going to do and what's the governance behind it. Who are the decision makers, when there's a bad actor what are the penalties out there. If people know up front what they're going to be expected to meet in the way of becoming part of this and asking a question what happens when there is misuse, because we all know at some point there are bad actors out there, so governance. And I think we need to have a really indepth conversation perhaps in the Tiger Team or maybe there's the Governance Workgroup that needs to look at what's the governance around this whole pilot project. And that needs to be very articulated, very much.

Paul Egerman – Software Entrepreneur

That's an excellent comment. And that's why we have this sentence here, ONC should use the experience of the pilots to help inform the type of governance that's needed. And we agreed –

Deven McGraw - Center for Democracy & Technology - Director

Yes, and we assume it's governed by government in the pilot phase.

Paul Egerman - Software Entrepreneur

Yes. We agree that that's a major issue. That was in Rich Elmore's presentation, so your comment there is excellent and the pilots I think will help us get the learning we need to determine how best to do that. Because what ONC is doing is really terrific. It's terrific from a privacy standpoint because it's really intended to address some of these concerns about the data, as I call it, flying around. We want to keep things as much as we can behind the walls of the provider and so that's what it's trying to do. It's not an easy project and there's a lot of things we just don't know the answer to. And it is a pilot project and so they're also doing a great job in asking our views of this to help inform them. This is just, as Judy said, there's to be iterative questions and this is an iterative process. As we learn we'll be coming back and forth and talking about it some more.

Farzad Mostashari – ONC – National Coordinator for Health Information Technology

I wonder, Marc, if you had some thoughts on the governance side with the experience of the Care Consortium and whether there can be ways of taking the learnings from query and having affinity or other distributed governance as a model based on your experience.

Marc Probst - Intermountain Healthcare - CIO

Well, as you know we're very early in the Care Consortium, but the governance processes are iterative as well, we're learning through the processes as we begin to start to share the data between those organizations. I don't know that I have anything good, explicit recommendation. I came in late, so I hate to say too much because I know I missed a lot. But the recommendations I've seen here look pretty solid that the Tiger Team's put together for an initial pilot, and we will learn and they will change.

Paul Egerman - Software Entrepreneur

I have a question, on your first recommendation and the premises, the data holder has the ability to run or not run a guery, so that permission is done at the guery stage versus at the organization, so you don't permit all queries in this organization to be run, or is there a process to have this query run, so presumably that's a human involved effort.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Yes, I would assume so, although you could foresee if you were an institution and you said I just love Query Health, I'm going to do all of them regardless, auto, on end, you could do that. That would be your decision institutionally. We assume that most institutions will want to either vet them individually or vet classes of them.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

We're running late on time. It's been a fascinating discussion. I heard two proposed, well, at least, I quess the question is in terms of whether there's all or part of these recommendations that we can move on now, two proposed amendments or additions that I heard. One was Josh's request to clarify the statutory authority piece and -

Deven McGraw - Center for Democracy & Technology - Director

And

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

And consideration of feasibility, particularly in emergency situations under public health authority, again. And the second was the issue of whether different kinds of queries, and in particular one dividing classes, queries that return summarized data versus queries that return line level, albeit de-identified data, might have different -

... data use agreements.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

Requirements, policy guideposts.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Right, restrictions on the back end.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

Yes.

Deven McGraw - Center for Democracy & Technology - Director

Right.

Joy Pritts - ONC - Chief Privacy Officer

This is Joy. The third point was the clarification that it was a query and follow up query.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

Right, or a series of queries.

Joy Pritts - ONC - Chief Privacy Officer

A series of queries.

As part of a purpose, an approved purpose.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Yes, right. So I think those are the three points. So maybe we start out with the affirmation about the public health is that nothing here in any way interferes with the statutory authority that public health

agencies have about their data, and that the practices remain the same ... only as identifiable as you need.

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

And if feasible.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

And if feasible. So the second one, do you want to discuss about the amount of identifiable data that's passed?

Deven McGraw - Center for Democracy & Technology - Director

No, I think there's a clump of issues around what recipients can do with data. And right now it's stated, in a very stark way, that recipients can only use it for the Query Health response, and Judy raised a concern that that wouldn't allow people to reuse it in order to formulate a better and more specific question nor a follow up question, which is clearly not what we intended. And others have wondered whether there ought to, and I proposed that maybe we instead articulate this in terms of that any query, or classes of queries, be matched with permitted uses by the recipient and that no others be permitted and that be part of the data use agreement, and then we could add in the point that we presume there will be a distinction between summarized and line level data, whatever line level data.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

So are people clear on those revisions to the originally proposed recommendations from the team? Charles?

Charles Kennedy - WellPoint - VP for Health IT

I just have one quick point. So on recommendation two, we're saying that the data use agreement is required even with de-identified data, which is a standard higher than HIPAA, is it not?

Deven McGraw - Center for Democracy & Technology - Director

Yes, it is.

Charles Kennedy - WellPoint - VP for Health IT

Are there other things we're doing in here that are higher standards than HIPAA?

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

To the extent that we're encouraging that a public health use might be done with aggregated or deidentified data versus identifiable data one could argue, well, actually it's not a higher standard than HIPAA because even public health users are subject to minimum necessary. So I think it's just in the agreement for data use.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, I entertain a motion for the revised recommendations from the Tiger Team.

M

. . . .

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

And second? Any further discussion? All in favor?

М

Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Any opposed? Any abstention? Anybody on the phone that's a voting member?

Art Davidson - Public Health Informatics at Denver Public Health - Director

Yes, Paul, I vote in favor. This is Art.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you. Okay, so the -

Frank Nemec - Gastroenterology Associates - Gastroenterologist

This is Frank Nemec. I agree.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you. So we have a vote of all yes and one nay. Thank you so much to the Tiger Team for yet another outstanding job. Thank you.

<u>Deven McGraw - Center for Democracy & Technology - Director</u>

Just so you all know, you just gave the Tiger Team back some hours on October 20th because we won't need to have a meeting now.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you.

Deven McGraw - Center for Democracy & Technology - Director

So thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, so that brings us to our next topic, pretty much on schedule -

M

...

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

No. We try to get closer and closer on how much time it takes for the Privacy and Security team to -

<u>Deven McGraw – Center for Democracy & Technology – Director</u>

This is one where Judy would have said, no, you'll need an hour.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

It will be like the software, you just double it and we'll get there. So the next update is from CMS on how we're doing with meaningful use, and Robert Anthony is here to advise us. And I think Robert Tagalicod is on the phone.

Robert Anthony - CMS - Health Insurance Specialist

Good morning, everybody. I'm Rob Anthony with the Office of eHealth Standards and Services at the Centers for Medicare and Medicaid Services. I'm going to do a status of programs, where we are with registration, payments, and some of the attestation information. I think some of you have probably seen at least a preview of some of this in the Meaningful Use Workgroup last week but we'll review a couple more things in depth here. It's good news and it's worth repeating, as of the end of September we had about 17,000 eligible professionals sign up for Medicare for registration. We had close to 7,000 eligible professionals on the Medicaid side, so September about 24,000 providers came to register for the program, which is about a 70% increase over last month and August itself was about a 40% increase over July, so we're definitely seeing that increasing trend that we were talking about last time. At this point we have about 2,400 hospitals registered for the program, which represents a little less than half of all of the eligible hospitals and critical access hospitals that can participate in the program, and I'm happy to say that year-to-date as of the end of September we passed the 100,000 mark for number of people registered who are participating in the program. The good news is also on the payment side. I'm going to break this down into Medicare and Medicaid. On the Medicare incentive side, and these are payments specifically for meaningful use, there were about 25 million in incentive payments to about 1,400 eligible professionals. That's an increase of about 36% over the number of EPs who received incentive

payments in August. So again we're seeing that continuing trend. In August, again, we paid about twice as many as we had paid in July, so we're at least seeing that continuing upward.

We made about 61million in incentive payments to 30 dually eligible hospitals, and you'll see this on both the Medicare and Medicaid slides, dually eligible hospitals is sort of our term for hospitals that can receive both Medicare and Medicaid incentive payments, but in this case the share is for the Medicare payment. So for the month of September we paid almost 90 million in Medicare incentive payments and since the first payments began in mid-May we've paid a little over 357 million in incentive payments for meaningful use.

You may remember my pie chart from last time. This will look fundamentally like the pie chart you saw last time. In fact, most of these percentages are exact. We would expect it to be this way. Obviously internal medicine and family practice are at the top of the specialty list as we would expect. Again, that other category, which is a pretty large part of the pie, with 22%, is either folks who don't have a designation of a specialty in our, we call it the provider enrollment chain ownership system, PECOS system, or it's a number of EPs and other specialties who haven't reached quite a critical mass to get their own slice of the pie here. Again, as we saw last time, we have a couple of areas, like podiatry and gastroenterology, where we were encouraged to see that we're continuing to have EPs who are in those specialties who are coming in and successfully attesting because there were some early indications that some of those specialties felt they were facing some workflow hurdles in implementing some of the meaningful use objectives.

On the Medicaid side, actually Medicaid made close to 30 million in incentive payments to about 1,400 providers. They've paid a little over 6,300 eligible professionals year-to-date. They made nearly 80 million in September in incentive payments to eligible hospitals. So to date for Medicaid over half a billion dollars in incentive payments for adopting, implementing, and upgrading to certified EHR technology this year. Again, our pie chart not fundamentally changed, a little bit higher on the physician side this month from the last time we looked at it, but as we would expect we have physicians and those practitioners at the top of that specialty list. And again, dentists at the 4% pie slice, which we're encouraged by because we did have some early feedback from folks in the dental specialty that there were some challenges for them in procuring an EHR and implementing it, so it's good to see that we've got some folks who are coming in and at least adopting, implementing, or upgrading a certified EHR into their practices.

Altogether for calendar year 2011, with the program having operationalized as of January 1st and a number of milestones, including opening CMS's registration attestation system, states that are still on boarding, we have 33 states that are up and running now, and we expect to have 46 states that will be up and running as of the end of the year. But with all of that we have paid a little over \$870 million year-to-date in incentives for the EHR incentive programs, and we're well on track to surpass paying out \$1 billion in incentive payments by the end of the year, if not by the end of October.

I want to go into a little bit of the attestation data and the format is going to look very similar to what we looked at back in August and you're not going to see huge differences but I do want to draw some attention to some of the highlights here. At this point, and you'll see the exact number on the next slide, we've collected data from a little over 8,000 providers who have successfully attested to meeting meaningful use. This is a pretty small sample size relative to the number of providers that registered, so I'm leery, and I said it in the Meaningful Use Workgroup and I'll say it again here and I'll say it again on the next slide, I'm very leery of drawing conclusions from these numbers. We talk about the very small end. This is a really tiny end compared to the total universe of eligible professionals that can participate. You will see that on average all of the thresholds were greatly exceeded. That's somewhat, I think, to be expected because we have a lot of providers here who are really the early adopters, the beginning cusp, the people who are quite possibly most prepared for it. So in some ways we would expect that behavior.

But it is important to note that even though you're going to see these very large percentages, every threshold, every objective had people who were right on the border line as well. So there is a distribution within each of those objectives. There's not a lot of difference right now between performance with

eligible professionals and eligible hospitals. As time goes on that may differentiate in different objectives, but right now we're not seeing a whole lot.

One thing that we can look at right now, and again I hesitate to draw a conclusion from this but let's just say that it's a trend we're watching. There are relatively few exclusions being claimed on average when we look across it. ... claim exclusions and slightly higher numbers for CPOE, ePrescribing and drug formularies, and since those objectives all provide an exclusion for providers who write fewer than 100 prescriptions during the reporting period obviously we're capturing some eligible professionals who just don't prescribe as a normal scope of practice. So that may account for some of what's there.

We're also seeing EPs in hospitals both have slightly higher numbers on average for exclusions to the public health objectives. This is reporting immunization data, syndromic surveillance data, and for hospitals it's reportable lab results. Some of this I think is because there are some on boarding questions, some of it is certainly availability of those public health agencies for all of those providers, and I'll talk a little more about that when we look at some of that data. And it is important to say that the payment year has ended for hospitals on September 30th. The hospitals run on a fiscal year reporting period and the end of the federal fiscal year, September 30th, but hospitals do have until November 30th, 60 days after the end of that payment year, to actually register and attest. So we may still see some more numbers come in for hospitals as we go through this.

At the time that we did this analysis we had a little under 8,400 eligible professionals who had attested, 8,000 successfully and 396 unsuccessfully. We had about 302 hospitals attested, all of them were successful. We talked about the small ..., that 8,400 is about 1.5% of all of the eligible professionals who potentially are eligible to participate in the program. So not only are we not, I think, at a statistically significant number, I told you I was going to tell you that we shouldn't draw any conclusion, but we're also not at a relative sample size where we're seeing a lot of different types of providers. Again, these are the very earliest of the earliest, so we may see some mitigation of this behavior as we move forward, we're seeing high percentages now, but we may see more people who are landing closer to that threshold as the more, I don't want to say average provider, but as the less prepared or people who are on the longer tail come in to this. It's also important to keep in mind that all we're seeing right now here are folks who are testing for the Medicare EHR incentive program. We don't have any meaningful use from any of the Medicaid side, so we don't really have any sense of what hurdles they're jumping, how high they're jumping it, or what the challenges are going to be for them. Again, as that information comes in next year we'll have a little bit more.

However, a question was asked of us about what conclusions we can draw from eligible professionals who have not successfully attested, and I think at this point we have such a small number that it's hard to draw that conclusion. We've got them spread over different specialties and it's hard to say whether that's individual to a type of workflow or a type of practice or a type of provider. Hopefully as time goes on we'll have more of a sense of that from the data, but as time goes on we're also engaging in some pretty active field research and surveys about some of the challenges that are facing providers, specifically, we just completed a survey of a number of physicians that we know had either registered for the program but had not attested, or who had begun their attestation and not submitted it and really had paused in their attestation for months sometimes. And we really wanted to discover what were the challenges, and it's my hope that maybe next time we come here we can talk a little bit about that, but there really is a range as we talk to providers of what is, I don't want to say keeping them at bay, but what is standing in the road for them as they're moving forward. They're not insurmountable obstacles, but they're definitely things that we know providers are facing now.

I won't go through each and every one of these, but just a reminder, we've broken these into the categories of each of these objectives and these our core menu fall into. When you look at the recording objectives these are several objectives at once, so we sort of aggregated that performance. It's the recording problem list, medication and allergy lists, the vital signs, demographic information, smoking status. The performance on all of these is relatively high. When you look at performance in these categories it's actually what we're seeing that the average, I guess you would say the average score is, so the average numerator over denominator for providers is reflected in that performance. The exclusion

is actually the percentage of providers who are successfully attesting but who are claiming that exclusion. Where there's a non-applicable it's because there's not an exclusion provided. Then for a deferral it's the percentage of providers who are not selecting that objective as a menu option when they make their selections and again where you see a non-applicable for a deferral it's because it's a core menu.

One of the trends that we're watching here is the number of folks who take a particular menu objective but also claim an exclusion to it. There's not anything within the final rule that prohibits someone from doing that, and so we were curious to see, I guess essentially how many providers are meeting the letter of meaningful use and how many are meeting the spirit of it. And the good news at this point in time, especially for these early attesters, is that the exclusion rate for people who are claiming this is relatively low. Again, it's too early to really draw a conclusion from this pool, but at least it's an early indication that people are genuinely engaging in menu objectives that they feel that they can meet and are not excluding their way out of that.

Again, we have pretty high performances here on most of these. The 48% always stands out to people because when we're looking at performances that are in the 70s, 80s, and 90s that 48% seems so much lower. It's important, however, to realize that the benchmark for patient education resources here is actually 10%, so 48% is exceeding it by quite a bit. And there's probably some mitigation here by the fact that not everybody is going to be the recipient of patient education resources. So it's probably never going to score quite as high as you're seeing some of these other objectives.

The care coordination, both of these for EPs are menu, and this is where we're seeing some of our highest deferrals at this point in time, and deferrals again are where a provider has chosen not to select that as a menu option, they're essentially deferring it to participation in Stage 2. The good news is that this as menu options are scoring very high in performance at this point in time. It's hard to say at this point in time why they are the highest percentage of deferrals. Part of this may be, and we talked a little bit about this during the Meaningful Use Workgroup testimony, part of this may be that these are the early adopters and it may be challenging to find people to do this type of exchange with. Part of it may simply be that if you are one of the early adopters and you're on boarding very quickly it may be easier to make practice workflow changes than it is to implement workflow changes that involve electronically exchanging with other providers. We don't really know at this point in time, and I think we're going to get more information about that as we move forward and we're certainly, as we move forward with some of our field survey, going to be asking those questions of people who were successful and why they didn't particularly engage in some of this.

Then again you're going to see this as we move into talking about eligible hospitals, the public health objectives we are seeing some higher exclusion in deferral rates on these public health objectives. Part of this may be because we have recently released some FAQs which more specifically detail under what circumstances a provider may claim an exclusion to this or may conduct a deferral. Part of it may be because we know that, as I said, some public health agencies simply don't have this available in all areas. And then part of it is a difference in transport method, either it's a difference in the HL7 standard, the public health agency takes one, the provider's EHR certified for another, or the way in which that is transferred into the public health agency is not the same, not that the certified EHR is using. We also know that some of the public health agencies are on boarding more slowly than others are. They're in the process of getting their programs going for electronic submission or they're in the process of making electronic submissions more widely available through a variety of formats, but they may not yet have reached that level. So we've heard, at least anecdotally, from a number of providers that while their state may take immunization data, they're going to have to wait until later this year or early next year to be able to submit it according to the transport method that the public health agency uses.

So again for eligible hospitals, we're not seeing a whole lot of difference in performance, still pretty consistently high. We talked a little bit last time about the menu objective incorporating lab results and the encouraging thing still here is that we're seeing a relatively low deferral rate on an objective that we actually anticipated might be a little difficult for hospitals to incorporate into their workflow or to make system changes in order to incorporate, and yet we're seeing a fair number of them actually selecting that

as an option. But again, these are the early adopters. They may be the hospitals that are most situated to effectively engage with that technology.

So again as with eligible professionals you see the patient education resource performance here is a little bit lower, for the same reasons, although it is relatively higher compared to what we're seeing with the EPs. Last time that we talked about this the electronic copy of discharge instructions performance was actually at 66%, so the jump to 95% is a marked increase. Again, though, it may be a small end so we may have had a few hospitals came in who really knocked it out of the park and that changed the average. This is the challenge of the small end, is that some really high performers move that needle very far away.

And we're seeing the same thing for care coordination as we saw with eligible professionals, some relatively high deferral rates. And again, for some of the same reasons we can suppose hopefully we're going to find out a little bit more about that as time goes on and hopefully I think what we're going to see, especially as more hospitals are working with their referral providers to secure certified EHR technology, that we're going to see more of those summary of care transitions, more of those medication reconciliations, and hopefully a consistently high performance in those areas.

The same again with the public health agencies, we're seeing some increases in exclusion rates and in deferrals because of the same reasons that we outlined before. Overall, a fairly high performance from early adopters. We would somewhat expect the early adopters to have pretty high performance, but a small end, can I say that one more time, a small end and the trends that we've identified now are the trends that we're going to be watching as we go forward to see does that continue to hold.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Gavle?

Gayle Harrell - Florida - House of Representatives

Thank you very much. We appreciate it as we move forward because it's just fascinating to really help us understand how we're moving forward. If we could, in that first chart where you give your summary of registrations and your summary of performance, if you could give us out of what total numbers we're talking about. For instance, if we have 88,000 eligible providers how many out of 800,000 so we can get percentages. We benchmark ourselves so we know if we've reached 1.5% maybe next month we'll be at 5%, so we know how we're increasing and so we're talking out of the total pool of eligible professionals out there who would be able to do this.

Robert Anthony - CMS - Health Insurance Specialist

Absolutely. The total available pool of eligible professionals who are both Medicare and Medicaid that we identified is about 550,000 eligible professionals, so we're looking at a little more than 20% at this point in time. For hospitals it's about 5,100 eligible hospitals and critical access hospitals, so again a little less than half at this point in time. But that is why when we talk about the number of providers who have successfully attested 8,000, when we compare that 8,000 to that 550,000 we're just looking at such a smaller number.

Gayle Harrell - Florida - House of Representatives

And that would be very helpful to us to know that and put it into percentages.

Robert Anthony - CMS - Health Insurance Specialist

Absolutely.

Gayle Harrell - Florida - House of Representatives

The total numbers and also percentages would be very informative.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you. Marc?

Marc Probst - Intermountain Healthcare - CIO

Thank you. Robert, this is great, and I think it's a great discipline. I'm looking at these numbers and some of the trends are pretty positive so I really appreciate that. As you suggest the end is pretty low and I guess it's more, Farzad, a question for you. Is there an opportunity for either us or HHS or ONC, they're the much larger end out there that haven't yet, and you had a really good meaningful use workgroup I thought last week and with some very good information that was brought in and it just seems to me a formal, kind of getting preemptive or ahead of the game, we know that there's challenges out there, how do we formalize that? And it is impacting the next stage of the meaningful use, like I said, Paul, because I think you've got a great workgroup, but I think we're only scratching maybe the surface. Maybe we're not. Maybe these trends are going to, they're not going to just take right off, but gut feel is that a lot of what we're seeing now are people that were very involved with EMR prior to the process and just what can we be doing as a committee to help facilitate keeping that trend up, not having some kind of end where we did see the people that were ahead of the game. Is there a formal program, or could we suggest, recommend a formal program to look more deeply into that and how we can facilitate, because this is great. We're definitely heading in the right direction.

Farzad Mostashari - ONC - National Coordinator for Health Information Technology

Yes, there are a few things that we can do given the resources we have. The first is some of the more simple comparisons based on data that we already have of the nature that Rob has done, and potentially some comparisons by state or other available information to see whether there are certain parts of the population that are less represented in those attesting or registering than represent the broader population of eligible hospitals or eligible professionals. So, that I think gives you some of the top lines, but it doesn't tell you the whys and it doesn't give you some of the more detailed information. I think for that we have to go to those who have the day in, day out shoulder-to-shoulder experience with the providers and the extension centers, as you'll hear, are going to be an important source of that, in some ways more qualitative understanding of what's going on with the critical access hospitals they're working with, with the rural health clinics, with the federal ... health centers, with the small practices, with the consortia, and to really get under the hood of what's happening. I think we're going to be hearing some more from there. There are also surveys, so the National Ambulatory Medical Care survey does ask some questions about intent to apply for meaningful use, there's a rich amount of contextual information available there, and we have supplements at the sample size. The timing of some of those surveys take a long time to do and to analyze and to wait and to get the results out, so we hope that we'll have some, certainly for the final rule, some ability to look at some of that survey information from 2011.

Marc Probst - Intermountain Healthcare - CIO

Okay, that's helpful.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thanks. David Bates?

<u>David Bates – Brigham and Women's Hospital – Chief, Div. Internal Medicine</u>

Thanks. I had two questions. One is the list of who's been successful public, and I can think of reasons to do that and not to do that. But one reason to do it is that people could then get in touch with people who have made it. And the second really gets to what Farzad just suggested, it would be helpful to have a sense of, for example, how many of the hospitals are big hospitals versus small hospitals, what regions are they from, that kind of thing, because that would help us figure out how people are doing and who's struggling.

Robert Anthony – CMS – Health Insurance Specialist

There will be a quarterly published list of providers for the Medicare program who have successfully attested and we will be publishing that quarterly list, well actually it will be through the end of September the people who have successfully attested to meaningful use, we'll be publishing that this month. So it should be publicly available relatively soon. I think that we definitely want to engage in the type of data breakdown that you're talking about. So there is a plan to start looking at how hospitals are stratified regionally, how we're seeing eligible providers stratified, and certainly working with ONC to look at that

REC data as well and see where potentially we have some providers, when we look at that 8,000 who have come and successfully attested and we look at the 114,000 that are registered for programs and then we look at the nearly 100,000 that RECs have registered as well, how much overlap is there, in what areas are those EPs and hospitals. We're certainly thinking along the same lines.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Christine?

Christine Bechtel - National Partnership for Women & Families - VP

I have two questions. One is the big picture and it might be more appropriate for Matt later on ... but I'm going to ask it anyway. I thank you very much for this information. It's helpful. I think it's notable that the two areas that we see the biggest number of exclusions or in some cases low performance is patient and family engagement, and care coordination on both EP and eligible hospital. I know that a lot of folks in the field had trouble with, for example, the transition of care summary because it was just so undefined. Are there other things like that from your perspective that we need to know about that might be easier fixes that are specific to the program like that?

Robert Anthony - CMS - Health Insurance Specialist

I think as we hear more from providers that there is some lack of specificity we've been using the FAQs as a way to do that sub-regulatory guidance, if you will, to provide that level of specificity. Sometimes when you're working on it from our perspective or ONC's perspective it makes perfect sense. You know exactly what you mean and it gets out there in the field and the workflow, you have to specifically draw for people this is what we meant here and this is what we meant there. What's interesting as we've looked at FAQs that we published or the questions that come in that we've decided to turn into FAQs is that we seem to have gotten past the main hurdle or the early hurdle of what do you mean by this, can you define this, and we're getting more program and operational questions now than we are getting can you define clinical summary for me. Can you define whatever it happens to be? I think that the guidance has gotten through and I think it's been helpful for folks to help clarify some of that. I think there's no doubt that there are times where not knowing exactly what to do in certain circumstances may have held people back, I think we see that most clearly in the public health objectives, where we clarified when one is able to take an exclusion, when one does a deferral based on what was available to the provider and what the on boarding was, and we saw, from August to September, at least in the hospitals we saw a real change in those numbers because of that, not huge, but enough to register that something significant happened. But in general it's hard to say based on what we have that X lack of specificity has led to Y result.

Christine Bechtel - National Partnership for Women & Families - VP

Let me ask just one quick follow up, which is specific to eligible hospitals' discharge instructions. That's a pretty high exclusion rate. It's almost two-thirds. Can you speak to that at all?

Robert Anthony - CMS - Health Insurance Specialist

The exclusions for eCopy of health information and eCopy of discharge instructions are both if a patient does not request an electronic copy of this and we've sort of gone back and forth over this as well. Again, without having a whole lot of data it's hard to know exactly what those numbers mean. It could mean that patients aren't interested in electronic copies of those things. It could mean that patients simply aren't aware that those are available. It's early enough in the program I think as time goes on with the program and as there's more of a public awareness we're probably going to see that come down more as people realize that they have the ability to ask for that.

<u>Christine Bechtel – National Partnership for Women & Families – VP</u> Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, we have two more, if you can keep the answers short, please. Charles?

Charles Kennedy - WellPoint - VP for Health IT

When the meaningful use guidelines came out several private health plans aligned their pay-for-performance incentives around meaningful use and the attestation process. It might be helpful, again, to Marc's point, trying to drive additional volume and additional adoption, if we could align those programs further. And it sounds like in your answer to David Bates that you are going to be making a list of physicians and hospitals public. Is there some way you can create a file and share that with health plans. I think that would help operationalize many of our P-for-P programs and make sure they're as effective as they can be in driving adoption.

Robert Anthony - CMS - Health Insurance Specialist

There will be a public file on our Web site, so they absolutely can do that, and I think to David's point, as we move forward we know, at least anecdotally that there are more coming. We know, for example, that there are Medicare Advantage organizations that are going to be coming in who have two to three times as many EPs who will be ready to attest as of the end of the calendar year, or at least within 60 days of the calendar year. And some of our surveys have also turned up that at least anecdotally we have a number of EPs who are waiting either to complete their 90 day period, they on boarded and they got their 90 day period in towards the end of the year. So we're really looking at December, January and February to see if we're going to see a pretty sizable spike of eligible professionals coming, because we have at least, again anecdotally, some early indications that we've got more coming.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you very much, Rob, that's very helpful and we look forward to it every month. Thanks a lot. Next, John, are you on the phone?

John Halamka - Harvard Medical School - Chief Information Officer

I am indeed. Can you hear me now?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Yes. Thank you so much for being patient with us. The floor's yours for an update on your summer camp.

<u>John Halamka – Harvard Medical School – Chief Information Officer</u>

Thanks so much. I just want to offer one comment based on the last testimony, that Beth Israel Deaconess had zero patients go to the health information management basement to get a continuity of care document given to them electronically, but 5,000 folks uploaded their ambulatory data to Microsoft HealthVault. So I think it is in our case an awareness not a capability issue. Summer of standards, this has been exciting. Between April and September of 2011 the HIT Standards Committee has had a meeting every three days. And, Paul, your committee works extraordinarily hard but I will tell you I think the HIT Standards Committee at least deserves an award for persistence. And what I'd like to go through in the next couple of minutes is what we did, why we did it, and how we tried to meet your needs. So are my slides up on the screen?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Yes, they are.

John Halamka - Harvard Medical School - Chief Information Officer

Okay, very good. So slide two, our logo for summer camp. No swimming was allowed. Go to slide three, just go through the six teams, and I'll go through their details, their charge, and what we came up with, Metadata Power team, chaired by Stan Huff, looking at ways that we can describe patients, provenance of packages of data, and security and privacy flags that optionally might be used, absolutely no need to use them. Next, the Patient Matching team basically offering best practices for ways in which patients could be matched from disparate databases and data streams, not specifically delineating demographic data requirements, but showing sensitivity and specificity of different types of data and different experiences across multiple institutions and studies.

Next slide, ePrescribing of discharge meds, how is it that we can ensure hospitals participate in discharge medication ePrescribing, slightly different standard set than traditional ambulatory ePrescribing.

Next slide, the Surveillance Implementation guide, as we heard from the last testimony there are issues of public health supporting different versions of different standards than maybe certified products, and part of that issue was there was optionality. You could implement HL7 2.3.1 or 2.5.1, there was not an implementation guide on the syndromic surveillance transaction, so you'll hear that we have now corrected all these issues, one standard for each domain of public health with no optionality.

Next slide, the NwHIN Power team, looking at both the NwHIN exchange and Direct mechanisms of sending data from point A to point B or pulling data and looking at all of the suitability of the standards in the entire nationwide health information stack for transmission.

So now on slide eight, the charge we were given by Doug Fridsma and Farzad last April is that we need to take a look at all of the Policy Committee recommendations for Stage 2 and examine, based on what we specified in Stage 1, what are gaps and additions as we need to get to Stage 2, are there updates that we need to make to the Stage 1 given that there have been technology advances, there are standards that weren't previously available that we could select, there have been donations like Kaiser's Medical terminology donation to National Library of Medicine that are now public domain, and let's figure out what's doable, what is it that we can, in Stage 2,include as good enough, mature enough, and tested enough standards that they could be nationally deployed. And to do this we had phone calls, meetings, hearings, federal register requests for information, Wikis, working groups, and the Standards and Interoperability framework, which inside ONC, you guys probably know, is a construct of bringing stakeholders from the community to harmonize and when needed even suggest new implementation guides that are going to be empowering. The Standards Committee hasn't been in the business of creating standards, it's been in the evaluation and recommendation business, whereas, S&I framework actually gets to the bits and bytes and can even create novel intellectual property where there are gaps. So we have those folks.

Let's look at slide nine. It was very clear that as we examined the experience with certification, and we've heard on some of the attestations that there were issues where standards may have been ambiguous or incomplete and so we were able to take a fresh look at all the experience that the country had with Stage 1 and then recommend refinements to standards and to certification criteria that we hope will make the next round of certification much easier, and then, as I said, associate the standards where necessary with the recommendations that you had for the Meaningful Use Stage 2 functional criteria.

Our ... chart, on slide 10, shows you month by month what we took as goals, where in addition to your recommendations we had PCAST and its recommendations for creating metadata envelopes around all kinds of packages of data exchange to identify patients and provenance of data and security flags. And each month we got preliminary recommendations, we talked through the direction and ended up finishing summer camp on September 28th with formal, written unambiguous recommendations on every one of these standards to ONC.

Let's go to slide 11, that deliverable on September 28th included the output of six power teams, which as I mentioned, met every three days, and also included an advanced notice of proposed rulemaking on this idea of the PCAST-like metadata that could be used in general to envelope any data transmission identifying the patient and the provenance of the data. In addition, we reported out on six standards and interoperability project activities on best practices for issuing certificates to create a trust framework for healthcare, giving some really good implementation guidance and also addressing issues and gaps with how the federal bridge could be extended so that when a provider or organization wants to send data to a government organization that has certain certificate requirements, we would have certificate compatibility. Importantly, the S&I folks worked on a transfer of care summary format that would be a single summary format for the country, one version, no optionality, and has worked very closely with HL7 and that is going through the standard HL7 ballot process now. And the end result will be the use of something called consolidated CDA, which takes the work that HITSP did, the work that IHE did, the work that has been done by numerous private groups on refining, transfer of care summaries, and HL7 itself, and put one standard implementation guide together that consolidates all previous work that has gone before it. The nice thing about it is it's templatized, so if we decide that it's important for transfer of care summary to

have a problem list, a medication list, an allergy list, labs, diet and activity restrictions, you'll lift those structured templates and fill them in with your details and assemble the document and you have a comprehensive, very easy to parse transfer of care summary. So that's very good work with great consensus.

Lab: Lab has always been challenging because there are so many use cases for it. You have the simplest use case, an EHR places an order, a lab has a single result, it goes back to the EHR, there isn't the so-called reflex order where a lab may initiate an order on its own as a follow up test, you don't have the lab being used for biosurveillance or public health, it's just a very simple EHR lab exchange. That's one case. A much more complex case is the use of lab for reportable lab to public health or use in clinical trials, clinical research, much richer data sets. So what happened, which was so wonderful, over the summer, was those from the American Clinical Laboratory Association, Quest, LabCorp, hospitals that generate labs for the simplest use case, got together with those from public health and those who need the more advanced use case and came up with a single implementation guide that works for everyone, incorporating the best of ELINCS, the HITSP work that had gone on previously in HL7, to come up with a single lab transaction for the country.

Provider directory has turned out to be very hard work, and that is there aren't robust standards widely deployed in the United States today for describing organization or individual provider directories in a standards-based fashion that's easy to implement and interoperable. There are multiple pilots and multiple experiments, and so the S&I framework did a comprehensive study and analysis and recommended pilots on two go forward approaches, one that is called HPD/LDAP. This is an IHE profile that leverages some standards that we've used for directory inside organizations in the past, but haven't been widely deployed to large scale between organizations, so pilot needed, and the use of something that Google, Microsoft, and other social networking organizations are suggesting is a good idea, the embedding of structured microdata inside Web pages that search engines can parse. So if you want to look for John Halamka and find his e-mail address and his special secure routing information, it is as easy as I put up a Web page somewhere, it is spidered by Google or Bing or Yahoo! and made available in the same sort of structured way that you've probably seen your search engines deliver information about restaurants or locations in a structured way. Again, not widely deployed, certainly not in healthcare, but worth experimentation. So in provider directories constrain the space some and gave some go forward pilot recommendations. Query Health, which you folks just talked about, project formation occurred there, so that's just in the very initial stages, and you've probably heard about the ONC effort to begin a data segmentation initiative and looking at ways where privacy preferences, in a granular way, can be supported by standards, so that's just begun.

Let's go through the details of what summer camp actually handed off to the folks at ONC as they begin their process of regulation writing. Let's go to slide 13. Metadata analysis, whether I send a clinical summary, a lab transaction, an administrative transaction, or a prescription, it's useful to know what patient does this refer to. And you can imagine that a secure payload of information is wrapped in an envelope that's completely consistent, so it isn't as if in a health information exchange you need to have sophisticated logic that can dissect the payload, the internal message, to discover what patient is this. It's because a completely consistent envelope is used regardless of the payload. So after much inspection of existing standards and consideration of possibilities the team came up with a very, very simple construct of using the plainest XML you can imagine, something called CDA R2 headers, but it's just basically name, gender, date of birth, phone number, very simple demographic XML to serve as an envelope. For provenance, again, very simple XML, this came from Beth Israel Deaconess Medical Center, and here is Beth Israel Deaconess' certificates to prove it using standard certificate technologies and simple XML.

Then for the privacy and security issues, this again a very optional field, may or may not be used, but the use case was something like this, it turns out many states have somewhat interesting consent laws, Massachusetts, for example, for HIV results has consented to disclose an episode-based consent to view, so you can imagine if we're going to send a package from point A to point B we have consent to disclose but then we need an optional flag in the envelope that says and before you open this envelope ensure you have patient consent to view. So it's, again, a use case that may not be used very commonly, but where you need to put some kind of flags in the envelope before the package is opened that CDA R2

XML enables that. And this was all published in that advanced notice of proposed rulemaking and public comments currently being reviewed.

Patient Matching Power team, slide 14, was this comprehensive review of all the work that's been done by Rand and folks in Indiana and the best practices in the literature looking at the demographics one might consider to include in a health information exchange envelope or in a transaction that goes between two training parties of any standards where patient matching is going to be required. And it's enough guidance so that an implementer like me can say, boy, I really want to achieve specificity that's quite high. I don't want to combine the wrong patients. I'm willing to tolerate a little less sensitivity. Occasionally I'll miss someone whose name is horribly misspelled, but I will never put together the wrong patients into a single package. It's that guidance that the country needs.

Slide 15, I'll recognize that Medicare Part D for ePrescribing specifies two standards, NCPDP script is typically used ambulatory EHR to pharmacy, but also HL7, and specific flavors and versions of HL7 that might be more used in a hospital situation, where imagine that a hospital has a pharmacy in its four walls, it isn't going through a Surescripts network to send ePrescribing information, it's going from one floor to another floor and hospitals use a lot of HL7 inside. So we came up with the specifications specifically to ensure that hospitals could participate in ePrescribing of discharge medications, but also be completely compliant with existent Medicare Part D rules.

Slide 16, and this one, again, very important. You'll see we've eliminated all optionality and all the public health transactions, no more HL7 2.3.1 at all, one standard implementation guide for reportable lab, immunization and syndromic surveillance, with no optionality so that every public health entity and every EHR will speak precisely the same language.

Next slide, 17, a huge discussion on transport of data between point A and point B. The NwHIN standards were evaluated, Exchange and Direct, completely independently evaluated, it wasn't a bake-off comparing the two, because they're actually for two totally different purposes, and we looked at a number of criteria, which is do the standards and implementation guides for transport as specified actually meet their needs, are they mature, and that is to say, well known how to implement it. Are they widely deployed? Has the industry adopted them and is using them in production? What are the alternatives? So we came to several conclusions and came up with some specific recommendations. One of the challenges that HITSP faced in its five years of life, it was never able to provide any architecture, you could only select standards.

The challenges, if you're going to transport data and you want to use e-mail type technologies, actually there's an element of architecture you have to support. If you're going to have a mechanism by which a central index of patients is going to be queried and then data is going to be federated and you're going to pull it from multiple sources, there's a sense of architecture. So we really wanted to think about what are some of the architectural models underlying health information exchange and of course structured and unstructured data are both the kinds of things you'll want to think through, and we found in looking at all the existent deployments to date, Exchange and Direct, that there are limited uses of these two approaches in production. It's certainly true that the Exchange standards, which are based on a number of IHE specifications, are used between organizations or maybe used regionally. We just did not find a lot of national scale activity, and of course DoD and VA use them to some extent. Direct pilots have been used and been very successful, but limited production use, but I will say with Direct there is seemingly great momentum and many, many vendors charging ahead with wanting to implement Direct.

The Exchange specifications in general are comprised of 10 parts and they tend to be a bit complex and multi-layered, and some of the elements of the Exchange standards we have concerns about their scalability at national scale, and that is they may work fine regionally or locally or between two EHRs in an organization, but national scale such things as patient discovery, searching for where a patient's records might exist, required querying every possible institution where records might live, and that has scalability issues. We also of course did look at where you could simplify and update some aspects of these standards and made specific recommendations.

Slide 19, what we said about Direct is that S/MIME and SMTP are very widely adopted and well understood standards. The use of the domain naming system to distribute certificates is not widely used but DNS as a technology is widely understood and scales extraordinarily well. So our conclusion on Direct is although its adoption has been limited, the risk to moving forward to using Direct at a national scale is low, and so we felt it is appropriate to move forward with further deployment of Direct. We did not that some of the existent standards in Exchange were under specified, making it challenging to pull one piece of information. I just want that EKG as opposed to the entire record from an institution, so additional work to be done. The conclusion on Exchange is there are good parts and certainly it's being used in places guite successfully, but to scale it nationally additional work and refinement is required.

Then finally, we did suggest that if you put Google, Facebook, Amazon, and Microsoft in a room and told them solve the problem of transport, they may very well come up with a different set of technology solutions and it is worth exploring what would be this modern, restful approach that's so common today in our social networking applications. But for now Direct is certainly a fine way to move forward and if it is chosen by CMS to include in regulation, it will ensure that in Stage 2 we would have a consistent, well documented way to transmit data from EHRs to EHRs, from EHRs to public health, and having that level of specificity is so important if we're going to require a threshold of 10% or 30% of transition of care documents sent from point A to point B, we need specificity.

Finally, a great body of work done on vocabularies, slide 20. The teams that worked on this were the Quality team and our Vocabulary Taskforce, and for all quality measures identified every domain in medicine that is used in the quality data model, problems, meds, allergies, labs, radiology came up with one singular vocabulary or code set per domain, very well specified, as well as a comprehensive transition plan to get us from where we are today to where we want to be, realizing that not every EHR or database is going to immediately go from ICD-9 to SNOMED or be able to support RxNORM, how do we get there, and so there's a very comprehensive and thoughtful plan. And all of this summer camp work was fully integrated into a set of certification requirements that have been handed off to ONC for every single one of the areas that you, the Policy Committee, had recommended be included in Stage 2.

I know that was a lot, but I do want to open it up for your questions and comments. I think it's been a great summer and I hope you're proud of our results.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you, John. That was really a tremendous amount of work by your whole committee and workgroups, answered a number of questions, getting down to just a lot of work. I want to open with one question that plagued us, is your transfer of care, which I assume refers to the summary of care document, is that correct?

<u>John Halamka – Harvard Medical School – Chief Information Officer</u> Correct.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

And so you're saying that you specified that summary of care, what the contents are and the format and the standards?

John Halamka - Harvard Medical School - Chief Information Officer

Correct. So it is a set of templates. The way to think about this is we have gone through as a country over the last 10 years an evolution where what we started with was very general, CDA, clinical document architecture, as a family. Then we said, oh, we're going to take the best of CDA and CCR, we're going to create the CCD. Oh, but that's not constrained very much. So then we're going to come up with an implementation guide called C32. Well, now with the consolidated CDA templates it's even more constrained, a series of templates that have just the information that is necessary for the transfer of knowledge from each domain of medicine that can then be assembled into a comprehensive transfer of care document to fulfill a variety of purposes. So, yes, a singular format and singular approach has been proposed that incorporates all the fine work of all of its predecessors and isn't a revolution, it's an evolution, it builds on what came before.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Good, we didn't know that it existed. All right, other questions? Marc?

Marc Probst - Intermountain Healthcare - CIO

John, this is Marc Probst. As you went through and created, and I haven't seen all the details of work that's come out of here, but there has to be criteria that were used to come up with certain standards or decisions. Was it the most technically feasible? Was it the path of least resistance for where we know the country is at? How did the various committees come up with those assumptions that drove them to the standards that they determined were the most appropriate?

John Halamka - Harvard Medical School - Chief Information Officer

What a great question. Doug Fridsma would tell you it's the path of least regret, and what he means by that is how do we choose a standard which is appropriate for its purpose, is well tested enough to be known implementable, which has implementation guidance widely available, is going to be maintained by a standards development organization as needs evolve and is going to fit in this constellation of other standards so that as a building block it is naturally going to co-exist and play well. I'll tell you we started as a Standards Committee two years ago with outlining a set of principles for all of this work and we've stayed true to that set of 10 principles through our summer camp.

Marc Probst - Intermountain Healthcare - CIO

Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Good. Larry?

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

I'll add to the congratulations on a really successful summer. I have some questions on the metadata, and this might be more for ONC because you guys didn't issue the advance rule, they did. But I was curious, on the identity piece it seems like we're using very traditional identifiers and I was wondering if in the discussions any other identifiers were considered. And I'm thinking about things, you mentioned in fact phone numbers, which are not in the ANPRM or e-mail addresses, so people are self-assigning, if you will, through all of their various commercial engagements, identifiers, many of which they keep for years and years and are very specific to them, so were those considered all in the discussions of the teams?

John Halamka - Harvard Medical School - Chief Information Officer

Doug, I think you're on the phone, any comments you would make? I'll say that certainly I think that all of the possible identifiers, including e-mail address, cell phone number, last four of Social Security, were all considered recognizing they had certain implications for sensitivity and specificity, accuracy, and what would be called the static nature of such data. How often does an e-mail address change? How often does cell phone number change?

Doug Fridsma - ONC - Director, Office of Standards & Interoperability

This is Doug. Thanks very much for a tremendous summary of all of the activities of your committee over the summer. We have gotten a number of comments, and Steve Posnack and Jodi probably could talk a little bit more about that. We are currently reviewing that to see if there are comments that would suggest other identifiers that could be considered. As part of the committee's deliberations they did consider a wide range of possible identifiers. They also looked at a number of different existing standards that were used to identify patient information, from HL7 to CDISC, to work that had gone on within the NIEM framework, and all of that fed into the identifiers that they looked at and considered.

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

Maybe this is a related question, I know we've got some lovely goals up there for specificity on patient match, specificity and sensitivity, and I wonder if there's actually been any good research on how

successful our current algorithms are, or if we're allowing anecdotes for people to say, oops, that's a mismatch.

<u>John Halamka – Harvard Medical School – Chief Information Officer</u>

I will forward you the work of the Rand Corporation that actually did that study with the entire Medicare data set and where 80 million people looked at what sensitivity and specificity one could achieve by the use of various demographic identifiers and the use of different algorithms. So that and other evidence was considered.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Great.

Deven McGraw - Center for Democracy & Technology - Director

Can I interrupt for a second. This is Deven. We also got testimony during our patient matching hearing from a number of entities who match Surescripts, some institutions, about the levels that they think they achieve with the algorithms and the processes they use. So the Rand study was a study on a database, and that testimony was relevant to what people are actually doing in the field as well, so I think those are potentially very good references. I just want to clarify with John while we're on this topic and then I'll stop, because Larry I didn't mean to interrupt your comment, but I took those assumptions on sensitivity and specificity to not be recommended levels per se, but assumptions that these were goals that entities might want to strive for and here are some best practices to getting to that level. Did I understand that right, John?

John Halamka - Harvard Medical School - Chief Information Officer

You are completely correct. You may choose other levels, but our sense from the industry was that many of the best practices indicated a desire to always combine that patient data which is from the same patient even at the price of sometimes missing some data. So here are a set of best practices should you wish to follow that approach.

Deven McGraw - Center for Democracy & Technology - Director

Thank you.

John Halamka - Harvard Medical School - Chief Information Officer

We did not dictate demographics that must be recorded or must be used, nor algorithms that must be used, but give enough guidance to enable wise implementation.

<u>Larry Wolf - Kindred Healthcare - Senior Consulting Architect</u>

I guess I'm on the theme of metadata stuff, that's where I stopped or something, where I had consistent questions from the earlier ANPRM and around privacy, so it looks like we're creating some notion of privacy pointers. Was that something that you guys developed, and could you expand a little bit on what the thinking was behind it, because I was a little stumped reading it in the rule.

John Halamka - Harvard Medical School - Chief Information Officer

Sure. As I mentioned for the use case that I identified that had a consents to view requirements before the envelope is opened, reading through the PCAST requirements that did include three kinds of metadata, that patient identifier, provenance, and the notion of a privacy and security flag, we simply tried to provide an optional set of standards that would meet the PCAST requirements and address use cases such as the one we have in Massachusetts, and what it does is it provides a URI, like a URL, that can point to a policy and then a flag associated with the policy that it points to. To be honest, we don't think that this actual construct would be used very often, but there are some use cases where it could be empowering, and so it's truly that simple. Here's the policy and here's the flag associated with the policy and we provided a code set that we pulled from HL7 of eight or ten additional kinds of flags that you might want to use.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

Okay, well, I guess I'll stop. Thanks.

W

... and I'd like to just follow up with that a little bit, is that the data segmentation project that John mentioned earlier is looking at the standards that were recommended. The standards that were recommended by the Standards Committee were recommended with a proviso that ONC conduct further testing on the standards, and so we are in the process of doing that.

Larry Wolf - Kindred Healthcare - Senior Consulting Architect

... of further testing, further testing, further testing. Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you. Gayle?

Gayle Harrell - Florida - House of Representatives

Thank you so much. I'm so excited about this, John, thank you. I can't believe that the summer has produced such a magnitude of work. It sounds like the Tiger Team's been on your back too. I really want to talk about where we go and what the direct practical implications are of what you have presented and what the Standards Committee is now doing in their – and I want to clarify, perhaps, Paul, you can clarify me, are we in the advanced notice of proposed rulemaking, or have we actually got a rule out there? What's happening on the recommendations coming out, are there –

John Halamka - Harvard Medical School - Chief Information Officer

Doug, maybe you can comment on this because the ANPRM was on the metadata only, there is two -

Gayle Harrell - Florida - House of Representatives

I'm sorry.

John Halamka - Harvard Medical School - Chief Information Officer

... and NPRM that incorporates all this material that I've presented and I understand that maybe a December/January time frame, but of course I have no inside information about this stuff.

W

Let me try to take that. We have an ANPRM that went out on metadata. That went over the summer. We got comments back. I think we're scheduled for next time to come back and let you all know the latest on that. The expectation is that we're working on our standards and certification criteria rule to tie it with Meaningful Use Stage 2. The target that we're shooting for is to have that out by end of December, early January, and anything from the ANPRM that we wanted to include in standards for the next phase would be included in that NPRM. So the only thing that John mentioned that we have put forward from ONC is the advanced notice of proposed rulemaking on the metadata standards, but anything from that would be packaged with all of the other standards that we would propose for the next phase.

Gayle Harrell – Florida – House of Representatives

Basically what we're looking at here are things that would be through certification standards be required for meeting Meaningful Use Stage 2.

<u>W</u>

We would be looking at the recommendations for our standards and certification rule, so, yes, they would be tied to the certification criteria for the next set of certified EHR technology.

Gayle Harrell - Florida - House of Representatives

So the next set that would meet the standard that you would have to have to -

W

... in place for Stage 2.

Gayle Harrell – Florida – House of Representatives

... for Stage 2.

<u>W</u> Correct.

Gayle Harrell - Florida - House of Representatives

So by Stage 2, and maybe, John, this is a question for you, by Stage 2 when we're up and running in Stage 2, what is going to be the impact on HIEs and health information exchange? Where do you see that going and how much of an impact will it have on simplifying health information exchange? And will we really be able to have those HIEs up and running doing the kinds of exchange we would want by Stage 2?

John Halamka – Harvard Medical School – Chief Information Officer

Let me put on a slightly different hat for you, one of my other roles is that I work with health information exchange organizations in the state of Massachusetts. And the state of Massachusetts examined the work of the summer camp and said, we as a state will create a backbone connecting every provider, payer, and patient in the state using the direct SMTP, S/MIME standard as it seems to be low risk, and transmitting the HL7 2.5.1 syndromic surveillance immunization reportable lab transactions to public health in the format as dictated by summer camp and adopting a transfer of care summary that will go from every provider to every provider in the summer camp format because they were so constrained that this was the one way to do it and it has impacted our entire health information exchange strategy for the state. I think our public health folks are overjoyed. There's only one message that they have to parse.

Gayle Harrell - Florida - House of Representatives

Terrific, thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Anything more? Charles?

Charles Kennedy – WellPoint – VP for Health IT

I noticed in your presentation that you identified SNOMED as the terminology that we're going to use moving forward. Is the standards team going to be looking at OWL or other languages for the development of SNOMED on a technology platform? Are you going to go into that descriptor logic space, or how are we going to operationalize SNOMED technologically?

John Halamka - Harvard Medical School - Chief Information Officer

The National Library of Medicine is currently the keeper of all cross-maps including the Kaiser converge medical terminology, which in fact is, as you described, how do I take a plain English expression a doctor would use, a plain English expression a patient would use, cross-map it to SNOMED CT, ICD-9 and ICD-10, and where appropriate LOINC, so that entire body of intellectual property is now in the public domain and being made available through the National Library of Medicine. It is the direction that the Standards Committee has recommended to ONC that NLM be the clearinghouse for all of those types of cross-maps and tools that would enable developers, providers and patients to have the ontology cross-walk that you've mentioned.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Wonderful. Well, on behalf of this committee and the rest of the country I want to thank your committee and the Power teams on a very productive summer camp, and thanks for sharing all that wonderful work, John.

John Halamka - Harvard Medical School - Chief Information Officer

Thank you. I'm always happy to serve the Policy Committee. So I look forward to working with you –

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

That's good. And thanks also for helping bring us within 15 minutes of our schedule. John Halamka - Harvard Medical School - Chief Information Officer Perfect.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

We will adjourn for a lunch break and return back at 1:00, please.

John Halamka – Harvard Medical School – Chief Information Officer

Thanks so much.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you, John.

(Lunch break taken.)

Operator

The lines are open.

Mary Jo Deering - ONC - Senior Policy Advisor

Ladies and gentlemen, the lines are open. We're going to be reconvening the meeting of the HIT Policy Committee. I would remind all members to please state your name when speaking for the transcription and for those on the phone. And a reminder also there will be a time for public comment at the end of this call. Paul, I'll turn it back to you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Wonderful, thank you and thanks for everybody coming back from lunch, or at least most people. We're going to begin with an update on the Enrollment Workgroup, and Kristen, I believe, is going to – no, she's on the phone.

Kristen Ratcliff - ONC

Yes. I'm here.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Great, thank you.

Kristen Ratcliff - ONC

Hi. I'm Kristen Ratcliff. I'm the ONC lead on the Enrollment Workgroup and I'm standing in for Sam Karp and Aneesh Chopra, who are the co-chairs of that workgroup, but were unable to join us today. I wanted to join for just a few minutes to provide you an update on the work of the Enrollment Workgroup. I think it's probably been a while since you've heard an update on the workgroup activities. Just for a little refresher on the historical background, the workgroup was convened in response to Section 1561 of the Affordable Care Act, which charged the Policy and Standards Committees with developing interoperable and secure standards and protocols for streamlining eligibility and enrollment in health and human services programs. So we put together a workgroup, and that workgroup made preliminary initial recommendations last September and since that time we've convened the workgroup around a number of areas. We held a day-long hearing in which we invited various vendors and states to reflect on our initial recommendations and to identify implementation challenges that they foresaw as a result of those recommendations. We continued work on the NIEM standards and using the NIEM standards to exchange data elements needed for verification of different pieces of information in a consistent way so that information could be more easily shared between programs and systems and in modules and applications and whatever might be needed for the various architectures that states might employ to implement the health insurance exchanges.

In April we completed an initial review of our first set of NIEM recommendations and did a little bit of a quality control check, a reality check and used guidance that was coming out from CMS to refine those estimates. We have also I think, probably at the last update you heard from us we provided an update, we were asked to evaluate some potential scenarios by CMS, some scenarios where data exchange between systems, for example, between one state and another state, between an exchange system and a Medicaid system, or an exchange system and a food stamps, a SNAP system, and we were asked to evaluate and provide guidance on that, and that guidance was passed through this group, the Health IT

Policy Committee, and then integrated into CMS guidance that was released. We have had a meeting of the Enrollment Workgroup last month and we will have another one next week. We had, over the summer, a lot of guidance and regulations, proposed regulations came out from CMS, so we've done a little regrouping to hone and refine our standards and the way forward. We anticipate that our work moving forward will be much more technical in nature as we move into implementation phase, so we are reconvening the workgroup and looked at standards and protocols that we released and identified to some implications for the technical implementation and also specifically five areas where we feel the workgroup can continue to provide value to CMS and the HHS work by a whole. The first is state and federal hybrid approaches for establishing and operating the health insurance exchanges. The second is cost allocation, so HHS was granted an exception to an OMB guidance which allows for states to cost allocate costs for upgrading human services programs. So previously all of the costs were allocated for health programs and now the guidance has been expanded, so that's an area where we feel the workgroup might provide guidance. The third is the NIEM standards, as I mentioned before. The fourth are APIs and applications for third parties or assisters to connect to state insurance exchange systems. Then the fifth is interface specifications. There are a number of data exchanges and visions by the proposed rules that have come out, and we believe that there might be some standards work related to the interface specifications.

As we move into the more technical phase of this piece we do plan to propose that the Standards Committee develop and implement a sister workgroup so that the workgroup that currently exists under the Health IT Policy Committee will continue to exist, and to provide policy guidance on the five areas that I just listed. But we do anticipate that there will be some fairly detailed and technical standards work that will be needed and so we are in the early stages of identifying what a charge for the sister Standards Committee Workgroup could look like, and identifying members and going through the whole process of setting that up. We think that the flow of information between the Policy Committee and the Standards Committee will continue and that the Policy Committee will inform the work of the Standards Committee in this area.

So that's really the main update. I don't know, is there any questions? I'm happy to answer any questions anyone has.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thanks, Kristen. Josh has a question.

<u> Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u>

Hi, this is Josh Sharfstein from Maryland. States that are interested in pursuing health insurance exchanges have to be essentially ready by January 1, 2013 and so the states are really building their systems now to accomplish that. How do you imagine all the standard setting fitting in with the fact that we're moving now to develop these systems. When do you imagine the standards will come into effect, and how would that engage with the fact that the eligibility systems really need to be built in the next few months.

Kristen Ratcliff - ONC

That's actually a question that we've, as you might imagine, been grappling with as we've been thinking about the fate of the workgroup moving forward. What we've heard from CMS and from vendors in states that they work with is that states are moving forward with their RFPs and their plans for the technical architecture, but that essentially they are incorporating placeholders for some of the Section 1561 standards. So the proposed rule would require states to comply with standards under 1561, and since we haven't yet gotten into some of the technical implementation things that we are proposing to do in this next phase from what we understand, particularly in the area of NIEM states are essentially waiting on guidance from CMS or from HHS, from us, to implement those standards. So we recognize that the train is about to leave the station but every indication that we've gotten is that it hasn't quite left yet and that there's still work to be done.

<u>Josh Sharfstein – Maryland Department of Health and Mental Hygiene – Secretary</u> I guess my question is what is your timing?

Kristen Ratcliff - ONC

We're still working that out with CMS and ... based on policy decisions that are remaining and the plans moving forward some of their RFP timelines. So I think we expect to move very quickly and we understand that whatever we do would be probably within the next, I would say, six months, six to eight months that we would need to produce a product that could be potentially tested or piloted.

Josh Sharfstein - Maryland Department of Health and Mental Hygiene - Secretary

Okay, I'd just encourage you to realize that we've got to be done by January 1st of 2013, so it's really important, the things that people think need to be incorporated, that we really know about it as soon as possible.

Kristen Ratcliff - ONC

Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you. Gayle?

<u>Gayle Harrell – Florida – House of Representatives</u>

When you mentioned the SNAP program or EBTs, are you anticipating that states would be required, in order to participate, to have to update their internal systems that determine eligibility?

Kristen Ratcliff - ONC

No. The proposal we're making that CMS put out delineates between vertical integration and horizontal integration. Vertical integration is the focus of this main push to get the insurance exchanges off the ground, so that the integration between Medicaid ... and the exchanges, and then horizontal integration with other human services programs is certainly strongly encouraged but is not required for the initial phase. But our Section 1561 of the Affordable Care Act essentially is the link to human services, so we do plan to consider how human services can be included or incorporated moving forward.

Gayle Harrell - Florida - House of Representatives

To determine whether someone is eligible for Medicaid it would then have to go through whatever system the state is using to determine that. Would that have to meet the same standards if we're using through the State Department of Children and Family, and does our eligibility on Medicaid, as well as EBT or SNAP, by default then if you have to do Medicaid eligibility using those standards is there going to be money attached to that to pay the states to do this?

Kristen Ratcliff - ONC

I think it's difficult to answer the question without understanding the specific architecture. At this point the requirements of the regulation are just integration between exchanges, Medicaid and CHP, and if the state has a system that is integrated with other human services programs already, I think that that's a more specialized question that CMS would probably need to address.

Gayle Harrell - Florida - House of Representatives

A follow up on that one, for the Medicaid eligibility then, which has to integrate with the ... and your exchanges, is there money attached to that?

Kristen Ratcliff - ONC

Yes. CMS is running a series of grant programs so they've put out early innovator grants which target a number of states who are going to do the IT prototyping for the insurance exchanges. There are also establishment grants and planning grants that CMS has put out for funding. At this point all the funding opportunities exist within CMS and they are responsible for determining what conditions are attached to those opportunities.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, any other questions? Kristen, at what point do you need some feedback or input from the policy group?

Kristen Ratcliff - ONC

Yes, I think the next step is just to, we have our Enrollment Workgroup meeting next week and we'll begin to identify – the NIEM standards in particular are moving fairly quickly, so we're just internally circling the wagon on specific business requirements with CMS, and I would anticipate that probably within the next three to four months we might have some initial deliverables to circulate to this body and get feedback on.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay. And you hopefully will have the HIT Standards Committee Workgroup up and running by then, correct?

Kristen Ratcliff - ONC

Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

It strikes me that a lot more of these decisions are in their bailiwick, is that right?

Kristen Ratcliff - ONC

Yes, at this point since we're moving into more technical aspects of this.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Okay, any other questions, comments? Thank you very much, Kristen.

Kristen Ratcliff - ONC

All right, thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

All right, and now we're up to our final presentation, an update on the REC program, we've heard a lot about it, we've even heard a testimonial from Farzad about how it's helped people, and Gayle has also reported that the Florida one is doing well. There's some good stuff going on and hopefully you'll update us on the work of the REC program more broadly.

Mat Kendall - ONC - Director, OPAS

Thank you very much for this opportunity to come here. Hi, my name is Mat Kendall. I am the Director of the Officer of Provider Adoption Support, which we lovingly refer to as OPAS. And I'm very happy to be here today to talk to you. I'm here today with Kim Lynch, who's the Director of our REC program, and what we're going to do today is talk a little bit about our office, which has responsibility for the regional extension center program. But there are a lot of other programs involved in our work as well, and I think the goal of us is really to look at ways in which we can help all providers to get to meaningful ... EHR system. Our general philosophy is that whether you're starting on a paper-based system or you're already on an EHR you need a whole network of supporting assistance to get you to do all the things that you need to do to implement well, so whether that's just understanding the basics of what the system is, looking at how you can redesign your workflow, hiring the right staff, working closely with the vendor, looking at interoperability issues, privacy and security, and ultimately meaningful use there are a whole host of different services that are there.

So in addition to the regional extension centers, which is going to be the focus of our work, I'm going to talk a little bit about our community college workforce program, because I think we're also bringing in a lot of great new folks into the health IT workforce and trying to figure out ways in which we can even get those people better aligned with the needs out there. And I'm also going to talk a little bit about the work that we're doing with our Health Information Resource and Research Center, the HIRRC, and talk a little bit about some of the work that we're doing with other groups such as meaningful use. The point I just want to make about this whole program is our goal here is to get folks to meaningful use and beyond. I think we're really very focused on improved population health, improved healthcare efficiency, improved health outcomes, and I think what we do is create a foundation in which a lot of other things can be built on as we move forward.

Just really quickly, a brief update on the regional extension center program in general, there are 62 regional extension centers that cover the entire country. They're awarded in three ways, and their goal is to help 100,000 priority primary care providers to achieve meaningful use by 2014. To be in the regional extension center we actually had a funding opportunity announcement that went out, we got great response from a very diverse set of stakeholders, and I think this is very important because what we really are trying to advocate is that to be supportive of the needs of providers in a local area you have to have a local solution. If you look at our models, we've got all kinds of different organizations, from university-based programs; some of them are affiliated with schools that have done agricultural extension centers, some aren't.

These are some new universities that are out there. We've got QIO, quality improvement organizations have been historically working on this. We've got managed care companies that have taken the lead on this, health IT organizations, and even though these organizations are the lead organizations, I would say that the secret of all the regional extension centers is that they're a diverse set of stakeholders so they've spent a lot of time thinking about who the folks are that they're working with, making sure they have the right relationship and beginning to think about how they can provide the set of services that are necessary to get people to meaningful use. I think one of the definite focal points of the regional extension center program is getting on the ground support, getting into the offices to do this, because this is very, very hard. I don't need to tell anybody in this room, but moving the number of people we're going to be moving to meaningful use in a smart, organized way is a challenge. But we think the goal of meaningful use is really achievable and it's worth it.

So again just a little more information about the regional extension centers, each extension center has a defined service area, and in that service area they have a defined number of providers that they're charged with recruiting, helping get to use of an electronic health record system and then getting to meaningful use. And oftentimes with the regional extension center program you hear milestones one, two, and three and that's essentially what they are. It's recruitment, getting live on the EHR system, and then getting to meaningful use. And what we're trying to do is also make sure that in those local areas that they really are engaging hospitals, payers, and other resources as well, because we recognize that the regional extension centers don't have the dollars on their own to do all the scope that we want and we think that we have to be synergistic, so working with existing players, other organizations that are doing that, is all part of our strategy here. We really are trying to figure out ways in which we can scale, get as many people's support as possible as we go forward.

Again, I think it's important to think about this set of services that the regional extension centers provide. In our funding opportunity announcement we identified a core set of services, and these things range from implementation support, support with meaningful use, design, workflow, redesign, privacy, security, outreach, and the slide begins to describe it. But how those services are provided to the providers is really up to the regional extension center and up to the different models that are there. I think one of the things we are finding is that there are some models that work in some parts of the country, don't necessarily work well in other parts, but most of the time there are elements that do. And being able to connect our regional extension center with another regional extension center is part of our process of trying to figure out how we can do this smarter, better, faster. Because I think at the end of the day there's a lot of hard work that is involved, and especially when you're thinking about the providers that we're focusing on for this is really providers in priority settings ... areas they need a lot of assistance, they definitely need clarity, and they need the best practices possible. So I think one of the things that we'll be doing in the next couple of months is beginning to take some of the best practices that we've ... out from the extension center and begin sharing them more publicly on the ONC Web site. That's part of our strategy. We call it the 63rd REC, which is really getting the best practices out there, letting everybody get them and getting also feedback from people as we move forward.

From the extension center program we often talk about priority settings, and essentially what we try to do is use the dollars that we have allocated to target the providers we thought had the least likelihood of implementing on their own. So these are folks in small practices, less than 10 providers, public hospitals, ... hospitals, community health centers, rural health centers, and other medically underserved areas. This

is really strategic. We really wanted to focus on primary care providers because we thought they had fewer resources, but we also wanted to really make sure that we were not exacerbating a digital ..., and beginning to really focus on these folks that often don't have the resources that other organizations did was a very key priority for us. It's been maintained a priority, and I think it's very helpful to us because it helps us make sure that we're really targeting the people who need the best support.

And again once we're working with them I think the plan is to give them as much support as possible. So whether it's ... transition implementation or operating in the ..., these are all important elements of what the extension centers are doing. And I think it's important that wherever a practice is on the implementation road map there's support that they need to get to the next level, and especially when we keep thinking about getting to meaningful use and beyond, laying the infrastructure to support all of these other issues, working very closely with our other, not only ONC agencies but other federal partners to really make sure that we're getting the right resources out into the field is very important to us.

So where are we today? The good news is that we've got 96,000 providers and counting enrolled in the extension programs across the country. We've had fairly good enrollment in the last few months, we've been averaging about 6,000 providers enrolled collectively across the extension centers, and then that's been pretty consistent for about the last year. What we're very happy with is if you look at the distribution, really if you look at the small practice providers, that's 37%, but off of this consortium, which is practices that were formerly small practices that may be coming together because of AHCA, that's about 50% of the people we're talking. So the providers we really are looking at are in these small practices. We feel very comfortable about some of the other areas, for instance, the federally qualified health centers we think we're doing very well on there, and some other areas, such as our critical access hospitals I think we have a very clear way forward with that and going ahead.

So by and large we're very pleased with our enrollment. We think if we get to 100,000 primary care providers that's approximately about a third of the primary care providers in the country, so that's a good start if we're going for that smaller wedge we think that that is a place to go ahead. We recognize, though, that enrollment is only the first step and this is just the starting point. It's good to know the providers that we're working with, but we recognize that there's still a lot of hard work ahead. Only about a third of these providers are on EHRs at this point, the numbers keep growing, and that's really exciting, but we still have a very low number that are actually at that milestone three meaningful use. And what we're going to be doing with the program in the next year is really ... focus, not so much on the enrollment, although we'll continue natural enrollment and that is good, but really focusing on providing those comprehensive support services to not only implement but to upgrade systems and get to meaningful use and do all the hard work that's involved in that.

If you go to the next slide, just a couple of kudos to some RECs out there who have already exceeded their target, and I've got 12 of them right here, but in reality I expect about four or five, checking the numbers as I was leaving today, because some of them are really on the cusp and I think that you're going to continue to see very strong enrollment throughout the rest of the year. We're also doing a lot of focus on our critical access hospitals, we have supplemental grants because we recognize that critical access hospitals and rural hospitals have special needs and we need to begin focusing additional resources on them. So far we've got about 800 of them enrolled, and we still have many more to go, but it's good momentum on where we're going. I think one of the exciting trends that we're seeing is that some of the regional extension centers are beginning to really think about aligning with some of the NQS, National Quality Strategy programs. And from our standpoint this is really an exciting opportunity for us to partner with some of our other federal partners, such as CMMI, to think about how we can really get the biggest bang for our buck. For instance, CMS just recently with the QIO program incorporated a large element ... into the ... scope of work, and we're really now working with them to try to think about how we can get the RECs and the QIOs to really work together on that in a synergistic fashion. It's very exciting.

What I thought I would do now is just spend a little time describing four of our regional extension centers and giving you just a little flavor of how they're doing, because again each one is unique in terms of what their approach is, but I think these case studies should be able to highlight just some of the different models that are out there and give you a sense of what's happening. It's actually really fascinating to see

what's happening across the country. I'm starting up with the Ohio Health Information Partnership, OHIP, their extension center, they also receive funding from ONC for the health information exchange in Ohio They've got a long tradition of really working with a lot of the health IT partners in this state to really convene around health IT and have a fairly integrated strategy. So whether it's when they do RFPs they try to link to each other's work, try to think about ways in which they can supplement the HIEs thinking about how can we work with the RECs so when we're implementing a system it's building the infrastructure we want to get to in the future.

OHIP has also been very, very smart in terms of its strategy. What it's done is it's created little mini RECs, regional partners that are ... responsible for a subset of their target number across their state and they're providing even more localized support. So if you're in the Southeastern part of the state, in the Appalachian area there's a lot of activity, they've got huge enrollment out there, but they're providing very different services than they're providing in Columbus or Cleveland. I think what, from our perspective is very interesting is seeing how they're all bringing together the different programs and have a huge interest in their state. They've already, they've gotten over 5,000 providers enrolled, they're going to blow through their target, and over-recruit just because they have the need in their area. So that's very exciting.

The next REC I want to talk about is our South Florida regional extension center. This is an example of an organization that was a HRSA funded health center controlled network, or HCCN, prior to coming there focusing on really ... health centers and have really taken the opportunity to use the regional extension center program to expand their scope. And they're doing amazing work as well. Their initial target was about 1,500, but they got awarded in the first round and then they applied for more money to expand their service area in the third round, they're one of two RECs that did this, and they're already tearing through that target as well in terms of their enrollment. I think that that is really an exciting partnership, they've got lots of strong local ties, and they're also working with technology companies like Intel to do some marketing as well. I think you see a lot of the regional extension centers are really trying to figure out how to work with their local IT infrastructure, their community, trying to figure out how to take advantage of those services as people are going out there, if they can do things together it's a win across the board.

Next, I want to talk about our Nebraska regional extension center, Wide River, and I think what's amazing about these guys is that they've really taken us to heart and began by focusing on their rural providers. And at this point they're reporting that they've got 90% of their rural providers are in an extension center program, which is amazing. We still recognize that being enrolled does not mean you're in meaningful use, there's a hard way to go, but this is an example of an REC that's also QIO that really leveraged its existing relationships to get that focus and that commitment. And we're very excited to be working with them on that and thinking about also how we can take some of the models that we have that were used in other places and really develop them for rural communities. I think that they are doing a very good job of thinking about their community, again, working closely with their HIE and thinking about how they go out ... using both clinical and technical staff in a tandem approach, it worked very well for them. But they've got a lot of geography to cover, they're driving a lot of times in cars, so it's an example of the commitment that these folks are doing to getting to people and making sure we get the right providers out there.

The last regional extension center I just want to quickly highlight is our Los Angeles RHIO, there's a RHIO out there in Los Angeles, California, and this is a RHIO that –I'm sorry, RHIO. This is an extension center that is tied to the Medicaid managed care plan, so L.A. Care, and they have a different approach to how they're doing this. They have done a very targeted market segmentation in their area, they're using a lot of different data sources to identify the providers that were most at risk, so these were in medically underserved areas, and then they have flooded those areas and done extensive outreach to the providers in those areas to recruit them into the program. Again, I think they've done a very, very good way of thinking about how to bring the resources necessary from the local community, they've done extensive partnership in sub-models to bring in the right people, and rather than try to reinvent the wheel they've tried to take some of the existing resources out there, reallocate them and get them to the areas where they had the most impact. I think that they're also a very good example of where extension centers are thinking about looking at intermediate milestones to monitor the success of the different providers as we

get going. Again, enrollment is a good first step, but it's not the ... way, and LA is really thinking about monitoring the timelines it takes to do different steps, whether it's the most effective way of getting different practices, especially very, very small providers moving forward. Again, those were not meant to give you more than a flavor. I could put another 58 slides up there. The other extension centers, they're all doing innovative things across the board. And we're very excited for where they are in terms of the way in which they're moving forward.

One of the ways that we're really trying to leverage some of the lessons learned and best practices from the extension center program is through the HITRC, and the HITRC again is this virtual community that's really designed to take the best practices of the REC program, but also the other ONC programs, and think about ways in which we can facilitate sharing of information. So whether it's through the development of communities of practice, which are groups of like-minded regional extension center folks that get together to talk about issues and help identify best practices ... or other things such as regional meetings, trainings and what have you, the HITRC really is trying to get a comprehensive approach. And what we're trying to do with the HITRC really is to take the information that we've gone through and really begin putting it on the Web. So you'll be seeing a lot more of that from us in terms of getting these best practices from communities, different approaches, different ideas, different success stories, and migrating it forward.

The idea behind what we're trying to do is link together a lot of the different resources that we have through our program, so for instance the HITRC is taking a lot of the data that we collect as part of our routine project ... managed through the customer relationship management, or CRM tool that we use, which is Salesforce.com, and thinking about ways in which we can get that information and share it to use it to identify what types of services that we need, develop new tools, thinking about how we can share all this information on the Web site, and really support a variety of different knowledge sharing activities that are going on. I think this is a really great resource that allowed us to definitely take advantage of the good work that is out there, ... on it, but also identify areas that we need to continue to focus on, and I think through the HITRC we're going to be developing a lot of new tools in the near future to really help people with the nitty-gritty of getting to the final stages of meaningful use.

That's the regional extension center ... HITRC. I just wanted quickly to talk a little bit about the community college program. I know this wasn't officially on the agenda but I'm still proud of what they're doing and I wanted to slip it in here. The community college program, we've got five consortiums across the country and basically what we did was we gave out these five awards to ... consortium any two community colleges across the board. The goal is really to get 10,500 folks trained in these new fields as we get going.

If you go to the next slide, it really talks a little bit about what we're trying to do with these new roles, and we had another grant that helped develop the curriculum that's now on the Web. If people are interested you should go get it, download it, it's available, give us feedback, we're very proud of that. But these are really helping some of the skill sets, the concrete skill sets that we think we need for the health IT profession in the future. We're trying to get ahead of the game here, taking people with a healthcare background or an IT background and giving them another set of skills so that they can really begin focusing on roles such as practice workflow implementation, implementation specialists, implementation managers, and some of the technical skills as well.

We've done great work so far in terms of enrolling folks in this program. A lot of these programs are on line, so people are taking it at their own pace. We're seeing that there are a lot of people that are going through this program at their own speed. One of the interesting things about this is in terms of graduates we're seeing an older demographic than we wanted, averaging about 45 years old people going through this program. So these are seasoned folks, these are not people that are just coming out of school, but people with backgrounds, and we're doing a lot of incumbent workers, we're finding a lot of people are working on a job, taking this training, and using it to move up the ladder. And that's what we'd like to see. We want to see getting the skill sets out there. I think we still have a lot of opportunities to do a better job of internships for folks, so we're looking at ways of expanding the internship potential to the students, because you really need to understand healthcare, you've got to be out in the healthcare field, but I think

this is going on across the board. And we're seeing a lot of success across the country in each of our different programs in terms of getting folks through and getting them completed and moving them ahead.

That was a really quick overview of the extension center program and some of the other things at OPAS, and I'm more than happy to answer questions accompanied by Kim Lynch here, who can help me as well.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thank you very much, Mat. If the program has half the enthusiasm and energy that you have, we're in good shape. I think Eva had her card up first.

Eva Powell - National Partnership for Women & Families - Director IT

Thanks, and thanks, Mat. This is certainly exciting to hear about and I know that you all have been working really hard and obviously achieving some great success. Your presentation made me think about the testimony we heard last week in the Meaningful Use Workgroup hearing. We heard in that hearing a lot about workflow issues and since that is what you're working intensely on with providers, I wanted to pose this question to you because the testimony we heard focused particularly on patient engagement and care coordination and I think that's not a surprise because those are the areas that either aren't done particularly well or at all at this point in our history in our healthcare system. So obviously there's a lot that needs to change about workflows and in some cases there is no workflow, it has to be created from scratch. So my question to you is, given that, and also given the fact that ONC has recently launched a consumer campaign, I'm wondering what opportunities you see for having those two pieces work together. And as you were talking about the work that you're doing, it would seem to me like that would be an incredibly important partnership, particularly in the areas of helping providers meet meaningful use on the practice and workflow design, as I just mentioned, as well as potentially vendor selection, because not every product really does a great job in helping providers engage their patients. So just what opportunities do you see in that regard?

Mat Kendall - ONC - Director, OPAS

I'll start off with this and then I'll let Kim jump in, because I think workflow design is a continuous process. What we're really trying to get out there is that it's something you do when you begin the process, but then when you implement the process you've got to keep doing it. And part of it is getting at this whole continuous quality improvement ethos, that's part of what we're trying to do, and I think from our standpoint getting the extension centers to help educate people about this as an iterative process as you're beginning to work through things is very, very important and it's one of the central things we're driving for. I think the pieces about consumer engagement are right on. I think for some providers this is a new opportunity for them and they have to think through things in a standardized way. I think the extension centers, especially when we begin working on those concrete meaningful use objectives, some providers are going to be like how do I do this, and that's where an extension center can come in and start thinking about how to engage folks in that process. I think we have some innovative examples out there doing it —

Kim Lynch - ONC - OPAS

West Virginia, actually. West Virginia, the REC there has a CMS demonstration project right now that they are working alongside their REC scope to work in pediatric workflows in pediatrics, and I believe a cohort of pediatric practices so that certainly children and their families have better information, leading practices, but also have access to a personal health record. That's one example of ..., that's certainly something that we're looking to share more broadly with the RECs and I think, as Mat mentioned, through the National Quality Strategy and some of the forward-looking efforts that RECs are focusing on, consumer engagement and through ONC's efforts and many others in the meaningful use measures, we're seeing much more activity out of the RECs and just looking forward to fostering that at ONC and seeing where they take it and share with others.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thanks. This is really exciting. You said a couple of times that enrollment is only the first step, but I wonder to what extent you're going to be able to map the meaningful users to the RECs to see which RECs are most successful at getting large numbers of meaningful users, because that would be of great interest to us.

Mat Kendall - ONC - Director, OPAS

All the providers that we're working with have to get to meaningful use or we don't pay their regional extension centers. Milestone 3 is synonymous with meaningful use, so we have a way in which we can track that and we're working with CMS to also do the backtrack to confirm that cycle. I think what's most exciting is that a lot of the regional extension centers are really engaging with Medicaid providers or some of the folks that aren't in the system right now. We have some tools that we're deploying through the REC, through our CRM that will help us get some of that early data about how they're doing as they're working through the process that hopefully will be informing the discussions that we're able to have.

M

It would be especially nice to know, for example, how Medicaid providers in the small hospitals are doing.

Mat Kendall - ONC - Director, OPAS

Exactly. What we're also looking to do is help give that information back to the regional extension center, saying here's how you're doing, here's how the rest of the country is doing because there are those micro variations that are so important to understand and identify.

Kim Lynch - ONC - OPAS

And certainly where we have RECs that are demonstrating strength, as you're saying, really mining them for what they're doing and making sure that that information gets shared throughout RECs, but also through our HITRC and the NLCs more broadly.

Josh Seidman - ONC

Yes, I'll just add, this is Josh Seidman, I'll just add that one of the things that we're doing is because, as Mat was saying, on the Medicare side most of them are meeting their milestone 3 right through the attestations to CMS, for them to get that third portion of their payment on the Medicaid side what they need to do is they need to show us in some other way, and we've developed this tool that Mat mentioned through the ..., and what they're beginning to do is they're beginning to track those Medicaid providers. And over the next, I would say three to six months we'll begin to have enough data to start to look at that. We'll then take that data and integrate it with data that CMS is providing us and start to be able to look at some of the differences between Medicare and Medicaid.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Gavle?

Gayle Harrell – Florida – House of Representatives

All of this is very exciting, and I'm so pleased you used South Florida REC. I know Lisa Rowlings very well, who's the director there, and also have worked with her on many issues. One of the things that South Florida is doing that I'm very excited about is we are looking at actually becoming an HIE as well, and I think that is going to really link all these doctors together, and hopefully with the new standards we heard about today being available in Stage 2 Meaningful Use that's going to become even easier. But can you tell us, do you have any indication yet on how many other of the RECs are looking at also building in that HIE component? And are they doing anything to reach out to people beyond those providers that they already have relationships with?

Mat Kendall - ONC - Director, OPAS

Yes, I think about 12 of our regional extension centers also are state HIE recipients or closely affiliated with those entities, so those are natural alliances ... we're seeing, but I would say by and large all the RECs are looking at working very closely with their HIT coordinators in their state to think about how they

can align their work directly with the HIEs. So whether they're doing it to themselves or partnering together, we see this as a natural extension. The goal should be for the provider, the end user, to have as seamless, as easy an experience as possible. They just want to be able to get these things. They want someone to help them build a system that builds up to everything that they're doing so they don't get on what they think is an on ramp and find themselves off in a cul-de-sac somewhere. We want to make it easy for people to do the right thing, and I think that's what we're seeing a lot of the regional extension centers do, whether they themselves are being the facilitator or working very closely with other people, I think it's a core job of what we're seeing.

Gayle Harrell - Florida - House of Representatives

Excellent. Another question along the education component is the funding we're doing for our community colleges out there and getting our workforce up, because let me tell you I hear it on the ground every day, we need people in this field and there are such a problem getting trained workers, whether it's in the individual practices or the RECs, it's a major, major problem. And what I am kind of getting some feedback, and I'm at the grassroots level where they all come to me because they know I sit on this committee and I ... the state legislature, so I'm the bottom of the funnel, it all comes down to here, and what I am hearing from individuals who are doing a lot of this training on line is it's not practical. It is a lot of on line learning, book knowledge and whatever and it doesn't relate. Some of them do work in medical practices, do do IT already, but there's no hands-on direct contact and it's becoming a major problem, I think, and it's they're not going to be prepared to go out and solve the problems we're going to need them to be out in the workforce solving. How are you going to deal with this and what's your solution to that?

Mat Kendall - ONC - Director, OPAS

You're touching on something that I think we recognize, that you need these internships, you need to get people out there, you need people to be applying the knowledge they're having, especially if they're doing on line programs. What we're doing right now is we're really looking to reach out to healthcare providers out there who are articulating the need you're saying, saying, hey, I need some help, and figuring out ways in which they can offer some real life internship opportunities for these students. Because we've got the students, we've got the need, we've just got to figure out a way of linking them together, and this is ... we welcome opportunities to partner on that.

Gayle Harrell – Florida – House of Representatives

I think what I'm seeing also is you get a lot of quasi-trained people put into a situation where they don't have the answers, you need mentors, or you need not just internships but you need mentors and you need someone out there perhaps with more hands-on experience, who are actually directing these things.

Mat Kendall - ONC - Director, OPAS

Absolutely.

Gayle Harrell - Florida - House of Representatives

I don't know whether the RECs can play a role in that or what, but there needs to be a re-thinking of how you're doing it, because I can tell you right now I'm hearing it's not working.

Mat Kendall - ONC - Director, OPAS

Yes. So just an example of that, in Tennessee, for instance, they're working very closely with the state Department of Labor, the workforce board, and doing integrated programs with the REC in placement. Those are the types of models, you're absolutely right, that we need to get out there and replicate in other states.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Thanks, Gayle. Larry?

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

This morning we spent some time talking about adoption and we are, and very small numbers of people who tested so far, and it sounds like you're actually telling us that there's a fair number of people in the

pipeline who are making good progress. So any insights you can pass on or any thoughts you have about how to track where people are, short of they got to step 3 or they didn't?

Mat Kendall - ONC - Director, OPAS

As Josh will mention, we'll be having a lot more data in the next three to six months about the specific challenges folks are having. At this stage we've been focusing a lot on the startup issues, but moving people through the pipeline and just getting implemented on the system, so that's the beginning challenges, getting workflow in place, getting capital in place, getting vendor upgrades, things along those lines. I think we're beginning to see a shift, though, in talking about the specific challenges of hitting all the criteria and I think that we don't have a lot of data points on those specific criteria yet. I think we will begin seeing one more of that in the next three to six months, especially after January I think we'll see a big surge in folks that will be getting there, and we can have more detailed information then.

In terms of just some general high level trends that I'm seeing right now, I think that there is a lot of interest of providers in getting clarity on exactly what some of the details about the program are, and I think we've created things like a burning issues list among our regional extension centers to really help get that information out to providers, because there's a lot of stuff going on. Providers are being bombarded by not only, ... but ICD-10 upgrades, all this other stuff, and getting definitive answers is important. I think we've got to be cognizant that providers are very busy, they have a lot going on here, and they're being constantly bombarded. So doing the education work is going to be continually important to us. I think that we are hearing a lot of things about workforce, and again we've got to get these students trained and capable so they can meet these needs because that's very important. Then just the challenge of implementing a lot of these different practices and ... getting the right people out there. This is huge growth here and I think we're feeling a little growing pains as we're getting in that area trying to meet the needs that are being raised all over the place.

Kim Lynch - ONC - OPAS

But I would say that the biggest message that we certainly see now, and hopefully you see in our numbers, but also outside of the REC program what's happening in hospitals and in health systems and in larger practice groups is just momentum right now towards meaningful use. And as Mat said, we're working on better data every day. Certainly our program we're comfortable being able to give statistics on where the 100,000 providers we'll be working with are in the process, but that larger picture of those health systems of the larger groups, that's certainly something that we too would love more information on. But the sense that we have, the indications we have from the data sources we are able to access shows that the momentum is really moving forward but as far as the interim indicators that is absolutely something we're very interested in and we would be open to suggestions on.

<u>Larry Wolf – Kindred Healthcare – Senior Consulting Architect</u>

It seems like you're in a unique position where you're actually maybe two or three levels removed from the individual practitioners who are trying to get these systems up and running and so it's a much closer pulse, if you will, than we're getting from any other things. We get six people in a hearing and that's a ridiculously small sample size to extrapolate from. If you've got 100,000 that's a much better sample size.

V

... when you talked about the HITRC and the communities ..., so there's a very active meaningful use community practice, you mentioned the meaningful use burning issues workgroup so that's really to deal with issues about the rule and helping the RECs to help providers understand the specifics of each objective and the measurements and so forth. But there are several other workgroups within that community of practice and one of the things that we have done is we've used the community of practice not just to discuss things, but actually to create a set of really a work plan. What are the things that the RECs need and really helping us to help them to figure out what they need. So, for example, they identified not only a need for tools and resources, but some guidance for how to identify what are the right tools and resources for specific meaningful use objectives. And so we've now created this knowledge integration tool, which is an online tool which allows them to go online and find the right thing that meets their specific need through an electronic mechanism. There's a how-to manual that is going to be

published very soon which is going to really help people in walking through the various steps and they continue to identify specific things that will help them to move from point A to point B.

<u>Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO</u> Judy?

Judy Faulkner - Epic Systems - Founder Paul Egerman - Software Entrepreneur

I wanted to support what Gayle said. I think you were right on, Gayle, in your comments. One of the things that we see is that the speed with which you finish the training and go directly into the work utilizing what you learned is critically important. If there's much of a delay a lot of the learning is lost. And I was wondering if in future slides of these you could add on how many now have work in these areas so we can see that we're going from training to actually use of the training.

Mat Kendall - ONC - Director, OPAS

This is something we're very interested in tracking. Just the way our grant was, the community college, for that placement we have to have another run on top of it, but we're

<u>Judy Faulkner – Epic Systems – Founder Paul Egerman – Software Entrepreneur</u> Sure.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

M

Thank you very much for your presentation. Many people on the committee have postured that ... at the workforce level, and we're talking about community colleges, but I would also go to Gayle's point, which is are we reaching the current workforce, are we talking about introducing new bodies or retraining a small segment of our population and therefore not really getting to the core of where IT implementation really succeeds or fails? I guess what I'm going to ask you is what plans, what process, what marketing you have to address the current workforce to come to that next level?

Mat Kendall - ONC - Director, OPAS

We're actually seeing a lot of the enrollees in community college being incumbent workers. The Bellevue program, for instance, out in Washington State, they're in their 70s, I think in terms of their existing workers. I think that people in the workforce are getting the word about this. This is still a new program and we need to get the information out to folks. I think there is a communication plan we have to spread the word, because I think you're absolutely right, especially if workers the new skills, we need new expectations from them someone who understands that healthcare center right now is vital, especially in rural areas where you can't bring in other people, you've got to take the people you've got and give them the skills you need, and I think that's going to be very much part of what we're going to be advocating. We're ... across the board, because I think it's very important.

М

Just as a follow up, even just on the basic level of engagement of the workforce in terms of choosing of the IT system that's going in there, the training programs, things along those lines, these are basic, simple concepts that get lost when we talk about millions and millions of dollars and let's start off with these grandiose programs, but at the granular level it still has to be implemented at the workforce level.

Mat Kendall - ONC - Director, OPAS

..., absolutely.

Kim Lynch - ONC - OPAS

I would say that each REC has taken the training issue upon themselves in different ways and as they go into a practice or a critical access hospital they really assess the workforce in that setting to understand the skills of the providers and their staff and so forth to help round out where there are gaps to make suggestions in to community college programs, you have a nurse that really loves the technology, but

would love to do more than being that connector to help that person succeed. I've seen incredible individual heroics in implementations of folks who have never put together a training plan but gosh I guess I'll do it for everyone. So the RECs I've seen they really have been picking up that mantle and taking the skills that they have in house and helping translate them into the practices and the settings that they're working in, but also refer that same staff into other training programs so that they're able to develop their skills. So each is doing it a little bit differently, but certainly something that they've picked up as part of their charge.

M

In looking at your chart here, I'm from the Northeast so I'm curious why we're looking at a 50% dropout rate. Can you offer any explanation of what's different, because the rest of them are 25%, 20%, except for the Southwest.

Mat Kendall - ONC - Director, OPAS

I think some of the dropout rates have to do with specific colleges and that we're no longer participating in the Northeast.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO Gavle?

Gayle Harrell - Florida - House of Representatives

One more question, as we're moving forward in this are you working or do you anticipate working, not just with these community colleges, because these grants are running out, and what is the vision of where we go from here, not just training incumbent workers but really getting the message out to our colleges and universities that this needs to be part of the core curriculum of people coming up in healthcare, in IT, that it needs to be integrated into a general program out there at the university level so that we don't need to do retraining, we have the training pipeline in the

Mat Kendall - ONC - Director, OPAS

That is exactly one of the big discussions we're having right now. I think that there's a recognition that it's not just about implementing systems, but using systems to improve quality. That's the direction where we really want to see our programs evolving into. I think a lot of the community college consortiums really we get this already and are already beginning to say, hey, this was seed money to get us started, but to really be successful we need to think about training people to be workers in this new workforce and begin focusing on quality improvement. So for instance Cuyahoga Community College in Cleveland is doing a great job right now thinking strategically with university-based programs about that handoff, how do we create this pathway for folks, how do we begin focusing on quality improvement, because it's not just about IT, it's really about utilizing it in an efficient manner to get these outcomes, and that's where the shift has got to be, because when people start getting trained in that approach it becomes a lot more easy to fit into a lot of these new programs that are being developed.

Kim Lynch - ONC - OPAS

Again, I look at our 17 academic RECs that many of them have taken their role as an REC within their academic institution as an opportunity internally to educate other areas of their institutions. And in Illinois they've taken their small segment of REC work but are using that as leverage internally to have conversations about how to revamp med school curriculum, nursing school curriculum, and so forth, so again it's happening, I know about the micro level, the individual programs, the ... programs that again all of this activity is manifesting in different ways. But certainly some of our RECs are uniquely positioned to affect some of the curriculum.

Gayle Harrell - Florida - House of Representatives

Maybe this is a better question for the ONC, is where are we going on the national perspective of making sure that as people graduate from medical schools, as they graduate from nursing programs, that this is the standard of care and that we move forward so that you don't have to retrain, you are training from the beginning, and is there any kind of concerted effort to make that happen?

M

If I could just jump in there, I think we're engaging a lot of the medical schools, a lot of the certification bodies talking about meaningful use health and information technology, and ... working with... developing some continuing medical education programs for providers to keep them going in this area, because I think there's definitely a recognition that we need to get all of these programs focusing on the end goal of utilizing these systems to maximize the potential.

<u>Gayle Harrell – Florida – House of Representatives</u>

You're doing it down at the local level, you're doing it within this whole program, but I think there needs to be a larger look at that beyond this.

M

Yes, and ... certainly at ONC that we are working with various medical education bodies with the medical boards in particular, so actually at the meaningful use workgroup last week Kevin Wise is the president of the American Board of Medical Specialties ... and we can show you that testimony. But they're working a lot to think about how not only on certification of providers but maintenance of certification of providers includes an expectation around meaningful use. But these medical boards have said that over time that they expect that maintenance of certification will take into account that there's an expectation that part of being a medical professional in the 21st century is the meaningful use of EHRs.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Very good. Any more closing comments? Thanks again, Mat and Kim for a wonderful update, and an uplifting one at that. We can open up for public comments now, please.

Mary Jo Deering - ONC - Senior Policy Advisor

(Instructions given.) Any comments in the room?

Cheryl Bickford – American Nurses Association

Cheryl Bickford, American Nurses Association. To answer the question about the preparation of the clinicians and being able to use information system solutions and being information literate looking at evidence-based practice and so on, the nursing community has established competencies in relation to informatics to be integrated in the program for many years and is part of their accrediting program requirements for the schools of nursing. Just to let you know that.

I was listening to the input that's now emerging, the stuff that we're beginning to see that our practical instances, but I want to know if ONC has thought about capturing these pieces in a formal way so that it can be added to the evidence in the literature. We don't know which are best practices. We don't know whether a big bang is better than a staged implementation. We don't know about some of the change management sorts of things. Is there a mechanism to capture the science and the evidence as we're moving through this transition, this transformation?

Mat Kendall - ONC - Director, OPAS

Quickly, this is Mat Kendall with ONC. I think that is one of our key goals right now is to take a lot of the information we've gotten to process it and begin sharing it publicly. That's the 63rd REC concept. And I'd love to talk to you about how we ... do that.

Mary Jo Deering - ONC - Senior Policy Advisor

Operator, are there any people in the queue on the phone? Operator?

Operator

We have no one in queue on the phone.

Mary Jo Deering - ONC - Senior Policy Advisor

Thank you very much. Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

I think this has been a good day. It started out with an inspirational talk about partner ... transformation ... story that Farzad started with, and then he gave an example from the great state of California, of course only to close with the great state of Florida, so it was one of hope, both in having a vision of where we're going but also hearing the MU updates, the 70% month over month improvement and then to close with a pretty uplifting report on the RECs and at least where you would like them to go and who you want them to help. So I think things are going well but nobody stopped working at it. So I think it portends well. Thank you all for another productive day and we will see you next month.

Public Comment Received During the Meeting

- 1. I support Doug Fridsma's perspective that this data should be available as de-identified information. I would propose it also only be made available with the consent of the person (or their proxy) who the de-identified information is about. This consent could be fine-grained as well, as per the PCAST proposal.
- 2. The use of Data Use Agreements, e.g., as implemented by CMS and its Data Governance Board, may be well worth consideration on primary and secondary uses of the data.
- 3. There are technologies that insure that PHI is not provided (i.e. the data is de-identified) and yet, if ID is needed, a secondary query to the provider institution/provider/individual who can then determine whether they want to share that ID information. Quantal Semantics has been developing just such technology..
- 4. I have an idea while I'm sitting and listening to your discussion. The idea is to give data owner control of the record, and enabling each data owner having an 'electronic key'. The rule would be that unless the person invoking the query has the 'key' to the data, then query health only returns de-identified data. If the person invoking the query has the 'key' then identified data is returned. Patients will receive regular reports when their data has been accessed, and allowed to 'opt out' of that use of their data.